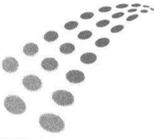


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MR#  
301166

Re: Section 8(e) Submission for n-Butyl Acetate (CAS No. 123-86-4)

Dear Sir or Madam:

The information below relates to butyl acetate (CAS No. 123-86-4) and is being submitted in accordance with EPA's interpretation of Section 8(e) of the Toxic Substances Control Act by the American Chemistry Council's Oxo Process Panel on behalf of the following producers of butyl acetate: BASF Corporation, Celanese Ltd., Dow Chemical Company, and Eastman Chemical Company. The information is supplemental to the letter submitted on behalf of the ACC's Oxo Process Panel on October 20, 2006 (attached).

The Oxo Process Panel is sponsoring a two-generation reproductive toxicity study on butyl acetate. Interim data generated by this study are being provided; the data referred to are preliminary and the Panel has not made a determination as to whether a significant risk of injury to health is actually presented by the preliminary findings. Nevertheless, this submission is intended to discharge any Section 8(e) responsibilities that might exist.

Following ten weeks of inhalation exposure to 0, 750, 1500, or 2000 ppm n-butyl acetate, the F<sub>0</sub> and F<sub>1</sub> male and female rats (30/group) were mated. Inhalation exposures continued throughout the mating and gestation periods. The following tables contain the weights for selected organs from the F<sub>2</sub> generation (necropsy of weanlings (PND 22) and necropsy of mature animals approximately 12 weeks old). The F<sub>2</sub> animals necropsied at approximately 12 weeks were directly exposed to n-butyl acetate from PND 22 through necropsy.



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Table 1 - Male F<sub>2</sub> pups at necropsy on PND 22.

Parameter	0 ppm	750 ppm	1500 ppm	2000 ppm
Final Body Weight	42 (5.1) <sup>a</sup>	39 (5.7)	39 (4.1)	36 (5.8)*
Brain (absolute)	1.4158 (0.05833)	1.4260 (0.07097)	1.3995 (0.06868)	1.3576 (0.07609)*
Brain (RBW)	3.386 (0.3266)	3.701 (0.4647)*	3.582 (0.2395)	3.846 (0.5159)*
Spleen	0.1532 (0.04092)	0.1413 (0.03855)	0.1460 (0.03891)	0.1221 (0.03998)*
Lt. Testes	0.0888 (0.01382)	0.0827 (0.01638)	0.0848 (0.01131)	0.0773 (0.01850)
Lt. Testes (RBW)	0.210 (0.0211)	0.208 (0.0173)	0.215 (0.0172)	0.212 (0.0234)
Rt. Testes	0.0896 (0.01463)	0.0855 (0.01734)	0.0866 (0.01236)	0.0775 (0.02011)
Rt. Testes (RBW)	0.212 (0.0228)	0.215 (0.0184)	0.220 (0.0187)	0.213 (0.0300)
Thymus	0.1702 (0.03214)	0.1520 (0.03008)	0.1419 (0.02722)*	0.1329 (0.03089)*
Thymus (RBW)	0.401 (0.0547)	0.384 (0.0525)	0.359 (0.0487)*	0.365 (0.0471)*
Thymus (RBRW)	12.010 (2.1011)	10.593 (1.8998)*	10.089 (1.5919)*	9.733 (1.9689)*

<sup>a</sup> mean weights (standard deviation) in grams

\* = significantly different from the control group at 0.05 using Dunnett's test

RBW = relative to body weight; RBRW = relative to brain weight.

Table 2 - Female F<sub>2</sub> pups at necropsy on PND 22.

Parameter	0 ppm	750 ppm	1500 ppm	2000 ppm
Final Body Weight	41 (4.7) <sup>a</sup>	38 (4.8)*	38 (3.2)*	35 (4.7)*
Brain (absolute)	1.3825 (0.06079)	1.3695 (0.05778)	1.3582 (0.06186)	1.3250 (0.05498)*
Brain (RBW)	3.408 (0.3036)	3.726 (0.4472)*	3.647 (0.2778)	3.810 (0.3723)*
Spleen	0.1555(0.03982)	0.1422 (0.03564)	0.1460 (0.02578)	0.1151 (0.03082)*
Spleen (RBW)	0.373 (0.0655)	0.371 (0.0597)	0.385 (0.0502)	0.322 (0.0513)*
Spleen (RBRW)	11.178 (2.6260)	10.328 (2.4475)	10.737 (1.8641)	8.644 (2.0981)*
Thymus	0.1756 (0.03287)	0.1524 (0.03193)*	0.1500 (0.02903)*	0.1402 (0.03198)*
Thymus (RBRW)	12.656 (2.0877)	11.081 (2.1765)*	11.004 (1.9491)*	10.547 (2.1883)*

<sup>a</sup> mean weights (standard deviation) in grams

\* = significantly different from the control group at 0.05 using Dunnett's test

RBW = relative to body weight; RBRW = relative to brain weight.

Table 3 - Male F, rats at necropsy on Week 12.

Parameter	0 ppm	750 ppm	1500 ppm	2000 ppm
Final Body Weight	375 (37.0) <sup>a</sup>	364 (33.9)	350 (33.1)*	325 (45.1)*
Brain (absolute)	1.95 (0.106)	1.96 (0.082)	1.90 (0.101)	1.82 (0.085)*
Brain (RBW)	0.523 (0.0469)	0.542 (0.0504)	0.547 (0.0478)	0.571 (0.0738)*
Pituitary	0.0139 (0.00414)	0.0122 (0.00208)	0.0130 (0.00338)	0.0107 (0.00179)*
Pituitary (RBRW)	0.716 (0.2056)	0.625 (0.1040)*	0.683 (0.1560)	0.589 (0.0933)*
Spleen	0.77 (0.132)	0.73 (0.099)	0.73 (0.098)	0.67 (0.125)*
Lt. Testes	1.57 (0.160)	1.53 (0.210)	1.57 (0.134)	1.43 (0.151)*
Lt. Testes (RBW)	0.421 (0.0428)	0.422 (0.0669)	0.452 (0.0472)*	0.444 (0.0377)
Rt. Testes	1.59 (0.158)	1.54 (0.212)	1.56 (0.145)	1.43 (0.152)*

<sup>a</sup> mean weights (standard deviation) in grams

\* = significantly different from the control group at 0.05 using Dunnett's test

RBW = relative to body weight; RBRW = relative to brain weight.

Table 4 - Female F, rats at necropsy on Week 12.

Parameter	0 ppm	750 ppm	1500 ppm	2000 ppm
Final Body Weight	241 (19.2) <sup>a</sup>	234 (27.3)	217 (26.8)*	213 (18.8)*
Brain (absolute)	1.83 (0.085)	1.82 (0.084)	1.77 (0.108)	1.73 (0.093)*
Brain (RBW)	0.763 (0.0690)	0.784 (0.0779)	0.822 (0.0705)*	0.818 (0.0602)*
Pituitary	0.0151 (0.00205)	0.0143 (0.00278)	0.0131 (0.00352)	0.0132 (0.00305)*
Spleen	0.59 (0.077)	0.57 (0.094)	0.53 (0.093)*	0.51 (0.084)*
Spleen (RBRW)	32.478 (4.0339)	31.276 (4.8220)	29.808 (4.4528)	29.323 (4.7319)*
Thymus	0.5542 (0.11525)	0.5344 (0.11647)	0.4689 (0.08380)*	0.4736 (0.10551)
Thymus (RBRW)	30.348 (6.1222)	29.393 (6.1874)	26.490 (4.4602)*	27.356 (6.1064)

<sup>a</sup> mean weights (standard deviation) in grams

\* = significantly different from the control group at 0.05 using Dunnett's test

RBW = relative to body weight; RBRW = relative to brain weight.

As noted, this information should be considered preliminary. If you have any questions regarding the information contained in this letter, please contact me at (703) 741-5609 or by email at [Barbara\\_Francis@americanchemistry.com](mailto:Barbara_Francis@americanchemistry.com).

Sincerely yours,

*Barbara Francis*

Barbara Francis  
 Managing Director, CHEMSTAR

cc: Oxo Process Panel members

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October 20, 2006

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Washington, D.C. 20460

Re: Section 8(e) Submission for n-Butyl Acetate (CAS No. 123-86-4)

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The Oxo Process Panel is sponsoring a two-generation reproductive toxicity study on n-butyl acetate. Interim data generated by this study are being provided; the data referred to are preliminary and the Panel has not made a determination as to whether a significant risk of injury to health is actually presented by the preliminary findings. Nevertheless, this submission is intended to discharge any Section 8(e) responsibilities that might exist.

Following ten weeks of inhalation exposure to 0, 750, 1500, or 2000 ppm n-butyl acetate, the F<sub>0</sub> male and female rats (30/group) were mated. Inhalation exposures continued throughout the mating and gestation periods.

The terminal body weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 558 (40.9), 519 (49.9), 454 (59.9), and 432 (63.2) grams, respectively. The absolute left testis weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 1.76 (0.264), 1.73 (0.110), 1.69 (0.146), and 1.59 (0.149) grams, respectively. The relative (to body weight) left testis weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 0.317 (0.0512), 0.336 (0.0396), 0.378 (0.0519), and 0.373 (0.0471), respectively. The relative (to brain weight) left testis weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 83.6 (12.2), 81.8 (5.7), 84.1 (7.2), and 81.0 (6.9), respectively.

The absolute right testis weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 1.77 (0.266), 1.74 (0.105), 1.66 (0.208), and 1.62 (0.127) grams, respectively. The relative (to body weight) right testis weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 0.319 (0.0519), 0.334 (0.0357), 0.372 (0.0638), and 0.381 (0.0460), respectively. The relative (to brain weight) right testis weights (SD) for the 0, 750, 1500 and 2000 ppm groups were 84.1 (12.4), 81.9 (5.4), 82.6 (10.4), and 82.7 (6.1), respectively.

The terminal body weights of the 750, 1500, and 2000 ppm were statistically significantly lower than the control group value. The absolute testis weights for the right and left testis of the 2000 ppm group were statistically significantly lower than the control group values. The relative (to body weight) right and left testis weights for the 1500 and 2000 ppm groups were



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8(e) Coordinator  
October 17, 2006  
Page 2

statistically significantly higher than the control group values. The remaining values were not statistically significantly different from the corresponding control group values.

As noted, this information should be considered preliminary. If you have any questions regarding the information contained in this letter, please contact me at (703) 741-5609 or by email at [Barbara\\_Francis@americanchemistry.com](mailto:Barbara_Francis@americanchemistry.com).

Sincerely yours,



Barbara Francis  
Managing Director, CHEMSTAR

cc: Oxo Process Panel members