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January 31, 2011

Via Courier

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Re: Toxic Substances Control Act Section 8(e) --
CAS Number 108-46-3, Resorcinol

To TSCA Section 8(e) Coordinator:

This letter is to inform you of the results from an Activated Sludge, Respiration Inhibition Test (OECD Test Guideline 209) under Good Laboratory Practice (GLP) with the substance resorcinol (CAS Number 108-46-3). This information is being submitted under Section 8(e) of the Toxic Substances Control Act (TSCA) to the extent that such information supports a substantial risk determination in accordance with current U.S. Environmental Protection Agency (EPA) guidance on Section 8(e) reporting or, in an abundance of caution, to the extent that such information may not support a substantial risk determination but nonetheless may be information in which EPA may have an interest.

The purpose of this test was to evaluate the inhibitory effect of the above test substance on the respiration of activated sewage sludge following OECD Test Guideline 209 (1984), "Activated Sludge, Respiration Inhibition Test, Method C.11 of the Commission Regulation (EC) No. 440/2008 and US EPA Draft Ecological Effects Test Guidelines OPPTS 850.6800 under GLP." In this test, activated sewage sludge was exposed to an aqueous solution of the test substance at concentrations of 1.0, 3.2, 10, 32, 100, and 320 mg/l for a period of 3 hours at a temperature of 21 ± 1°C with the addition of the synthetic sewage as a respiratory substrate. The rate of respiration was determined after 3 hours contact time and compared to data for the control and a reference item, 3,5-dichlorophenol.

The effect of the test substance on the respiration of activated sewage sludge gave a 3-hour EC₅₀ of 79 mg/l. The reference item gave a 3-hour EC₅₀ of 7.3 mg/l, and 95% confidence limits of 5.6 - 9.5 mg/l.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

INDSPEC Chemical Corporation

Barbara B. Buchner
Barbara B. Buchner



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Re: Toxic Substances Control Act Section Section 8(e) --
CAS Number 108-46-3, Resorcinol

To TSCA Section 8(e) Coordinator:

This letter is to inform you of draft results from an Acute Aquatic Test in Aquatic Invertebrates (OECD Test Guideline 202) under Good Laboratory Practice (GLP) with the substance resorcinol (CAS Number 108-46-3). Due to inconsistencies in the initial study, a second, definitive study was performed. The studies are still under review and the report has not been issued in final. This information is being submitted under Section 8(e) of the Toxic Substances Control Act (TSCA) to the extent that such information supports a substantial risk determination in accordance with current United States Environmental Protection Agency (EPA) guidance on Section 8(e) reporting or, in an abundance of caution, to the extent that such information may not support a substantial risk determination but nonetheless may be information in which EPA may have an interest.

The purpose of this test was to evaluate the immobilization of *Daphnia magna* of the above test substance following OECD Test Guideline 202, "*Daphnia* sp., Acute Immobilisation Test" under GLP. In this test, *Daphnia magna* were exposed to the test substance at concentrations of 0, 0.1, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, and 10 mg/L (nominal) in the definitive test in freshwater for a period of 48 hours at a temperature of between 20 - 22°C, and a pH range of 7.7 - 8.1 (one sample) with no treatment-related effects on dissolved oxygen. Test concentrations were verified at 0, 24, and 48 hours and ranged from 92% to 104% of the nominal value, so it was considered justifiable to calculate the EC₅₀ values in terms of the nominal test concentrations only.

The 48-hour EC₅₀ of the test substance in the definitive study is 1 mg/l with 95% confidence limits of 0.041 - 27 mg/L and the 48-hour no observed effect concentration (NOEC) was 0.32 (no immobilization observed).

Details regarding the Initial range-finding study, initial experiment, and second range-finding study are appended.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

INDSPEC Chemical Corporation

Barbara B. Buchner
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Supplemental Details

Initial Range-finding Study: No immobilization was observed at the test concentrations of 0.10 and 1.0 mg/L. Immobilization, however, was observed at 10 and 100 mg/L. Chemical analysis of the test preparations at 0, 24, and 48 hours showed measured concentrations to range from 91% to 114% of nominal indicating that the test concentrations had been correctly prepared. Based on these results, the test concentrations of 1.0, 1.8, 3.2, 5.6, 10, 18, 32, 56, and 100 mg/L were selected for the initial experiment.

Initial Experiment: Immobilization was observed at all test concentrations employed in the test which differed from the results of the initial range-finding test, which showed no immobilization at a test concentration of 1.0 mg/L. Chemical analysis of the test preparation at 0, 24, and 48 hours showed measured concentrations to range from 85% to 105% of nominal indicating that the test concentrations had been correctly prepared. Given this variation in the immobilization pattern between the initial range-finding test and the initial experiment, a second range-finding test was conducted.

Second Range-finding Study: No immobilization was observed at 0.10 mg/L. Immobilization, however, was observed at 1.0, 10, and 100 mg/L. These results were in-line with those obtained from the initial experiments thereby indicating that the results obtained from the initial range-finding test may have been erroneous. A review of the data could not reveal a reason for this given that chemical analysis indicated that the test concentrations had been correctly prepared. Based on this information, test concentrations of 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, and 10 mg/L were selected for the definitive test.

Definitive Experiment: 0, 0.1, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, and 10 mg/L (nominal).

Conditions: Photoperiod of 16 hours light and 8 hours darkness with 20 minute dawn and dusk transition periods. Some of the temperatures were measured to be slightly in excess of the 20 +/- 1C given in the study plan. This was considered not to affect the results of the test as no adverse effects of exposure were observed in the control daphnids throughout the duration of the test and that the temperatures were within the test guideline specification. The oxygen concentration in some of the test vessels was observed to have an air saturation value (ASV) in excess of 100%. This was considered to be due to the presence of microscopic air bubbles in the media super-saturating the diluents and was considered not to have had an impact on the outcome or integrity of the test as no adverse effects were observed. Test concentrations were verified at 0, 24, and 48 hours and ranged from 92% to 104% of the nominal value, so it was considered justifiable to calculate the EC₅₀ values in terms of the nominal test concentrations only.



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Positive Controls: Yes (potassium dichromate at concentrations of 0.32, 0.56, 1.0, 1.8, and 3.2 mg/L). The positive control at Harlan Laboratories is conducted approximately every six months. The positive control was dissolved in reconstituted water.

All study methods are consistent with those specified in the OECD TG 202.

Results and Discussion -- Definitive Study

Duration	Endpoint	Effect conc.	Nominal/Measured	Conc. based on	Basis for effect	Remarks (e.g. 95% CL)
24 h	EC ₅₀	4.7 mg/L	nominal	dissolved	mobility	3.4 - 7.3
48 h	EC ₅₀	1 mg/L	nominal	dissolved	mobility	0.041 - 27
48 h	NOEC	0.32 mg/L	nominal	dissolved	Mobility (No immobilization at this concentration)	

The slopes and their standard errors of the response curves at 24 and 48 hours were 1.8 (SE = 0.29) and 3.2 (SE = 1.3), respectively.

The reference substance (positive control) was within normal limits.

The EC₅₀ values and associated confidence limits at 24 and 48 hours and the slope of the response curve and its standard error were calculated by the maximum likelihood probit method (Finney, 1971) using the Tox Calc computer software package (ToxCalc, 1999). Probit analysis is used where two or more partial responses to exposure are shown.

All validity criteria were fulfilled.

Conclusion

Under the conditions of this study, the 48-hour EC₅₀ of the test material was 1.0 mg/L with 95% confidence limits of 0.041 - 27 mg/L and the 48-hour NOEC was 0.32 (no immobilization observed).

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