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Document Control Office (7407W)
US Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001
Attention: TSCA Section 8(e) Coordinator



Summary data — Direct Systemic Injection Test (ISO-10993-11) using Huntsman ALBAFIX[®] ECO

On September 23, 2010, the Textile Effects Division of Huntsman (Huntsman) received summary data from a Direct Systemic Injection Test (ISO-10993-11) using Huntsman product, ALBAFIX ECO. This data was provided by our customer, 3M. These results were apparently part of a larger study, performed at a contract testing laboratory, Toxikon Labs, for 3M. The summary data provided to Huntsman was an extract of the final report for this larger study, containing a robust study summary and related data tables pertaining solely to the testing of ALBAFIX ECO.

Huntsman is submitting this information pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). Huntsman has not made a determination as to whether a significant risk of injury to human health or the environment is actually presented by these findings.

These summary data are from a Direct Systemic Injection Test (ISO-10993-11) in mice dosed by intravenous (iv) or by intraperitoneal (ip) injection. Mice were dosed with single injections of 79.5 or 140 mg/kg of ALBAFIX ECO. Control animals received a single injection of USP 0.9% Sodium Chloride for Injection at 50 ml/kg. All animals that received intravenous injections of the test article solutions died immediately after dosing. All animals that received intraperitoneal injections of the test article solutions exhibited convulsions followed by death immediately after dosing. There were no signs of toxicity in the control animals. All animals that died during the study underwent a gross necropsy with no abnormal findings.

A copy of the ALBAFIX ECO data extracted from the Toxikon final report and robust data summary are attached to this report. Huntsman will provide to EPA any additional findings from this study that may be required pursuant to TSCA Section 8(e) reporting requirements.



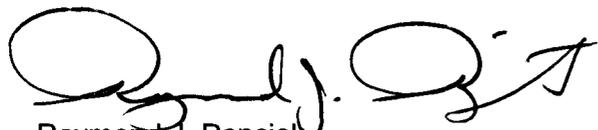
CONTAINS NO CBI

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CONTAINS NO CR

As always, if I can provide any additional information on the above study, please call me at (281) 719-3017, or contact me via e-mail at: Ray.Papciak@huntsman.com.

Regards,

A handwritten signature in black ink, appearing to read 'Ray J. Papciak', with a stylized flourish at the end.

Raymond J. Papciak
Manager, Product Safety
Huntsman International LLC

TOXIKON Direct Systemic Injection Test (ISO) results for Albafix ECO

Sponsor: 3M

Study Initiation Date: 7/6/2010

Study Completion Date: 7/9/2010

Final Report Date: 7/22/2010

Project Number: 10-3008-N1

References: The study was conducted based upon the following references: ISO-10993-11, 2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity. ISO 10993-12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

Comments: The Sponsor provided 4 Albafix ECO solutions for direct IV and IP injection. The test article solutions were stored at 4 ± 2 °C. The pH of the test article solutions was measured prior to dosing, and if necessary was adjusted using HCL to within a pH range of 6-8.

General Procedure: The Systemic Injection Study is designed to screen test articles for potential toxic effects as a result of a single-dose systemic injection in mice. Per Sponsor's request, the pH of all solutions was measured prior to dosing. The pH of solutions #5 - #8 ranged between 7.3 – 7.9; the solutions were dosed as received. The 4 test article solutions were injected intravenously (IV) and intraperitoneally (IP) at 50 mL per kg in groups of five mice. Similarly, groups of mice were injected IV and IP with control article USP 0.9% Sodium Chloride for Injection (NaCl). Mice that died prior to the end of the observation period underwent a gross necropsy.

Results: All groups that received IV injections of the 4 solutions contained mice that died or exhibited convulsions followed by death immediately after dosing: Solution 5, 3 mice (only 3 dosed); Solution 6, 3 mice (only 3 dosed); Solution 7, 3 mice (only 3 mice dosed); Solution 8, 3 mice (only 3 mice dosed). All animals that received IP injections of solutions #5 - #8 contained mice that exhibited convulsions followed by death immediately after dosing: Solution 5, 5 mice died; Solution 6, 5 mice; Solution 7, 5 mice; Solution 8, 5 mice. All animals that died during the study underwent a necropsy with no abnormal findings.

Conclusions: All the groups treated with the 4 test article solutions dosed IV exhibited biological reactions greater than controls. The groups treated with test article solutions #5 - #8 dosed IP exhibited biological reactions greater than controls. Therefore, the 4 test article solutions did not meet the requirements of the ISO 10993-11 guidelines for the Systemic Injection Test.

TOXIKON

Systemic Injection Test – ISO
 Toxikon Final GLP Report: 10-3008-N1
 Test Article: See Page 1

TABLE 1
 Animal Weights and Clinical Observations (Cont.)

Group	Animal #	Sex	Dose (mL)	Body Weight (g)				Weight Change	Signs of Toxicity*	Necropsy Obs
				Day 0 07/06/10	Day 1 07/07/10	Day 2 07/08/10	Day 3 07/09/10			
Albafix ECO, High Concentration, Solution 5 Test IV	41	Female	1.1	22.7	N/A	N/A	N/A	N/A	13A	None
	42	Female	0.9	17.7	N/A	N/A	N/A	N/A	13A	None
	43	Female	0.9	18.1	N/A	N/A	N/A	N/A	13A	None
	44**	Female	1.0	19.8	N/A	N/A	N/A	N/A	N/A	N/A
	45**	Female	0.9	18.2	N/A	N/A	N/A	N/A	N/A	N/A
Albafix ECO, High Concentration, Solution 5 Test IP	46	Female	1.0	19.9	N/A	N/A	N/A	N/A	3 A, 13A	None
	47	Female	1.1	22.2	N/A	N/A	N/A	N/A	3 A, 13A	None
	48	Female	0.9	18.3	N/A	N/A	N/A	N/A	3 A, 13A	None
	49	Female	0.9	17.3	N/A	N/A	N/A	N/A	3 A, 13A	None
	50	Female	0.9	17.5	N/A	N/A	N/A	N/A	3 A, 13A	None
Albafix ECO, High Concentration, Solution 6 (Autoclaved) Test IV	51	Female	1.0	19.6	N/A	N/A	N/A	N/A	13A	None
	52	Female	1.0	19.8	N/A	N/A	N/A	N/A	13A	None
	53	Female	1.1	22.4	N/A	N/A	N/A	N/A	13A	None
	54**	Female	0.9	18.5	N/A	N/A	N/A	N/A	N/A	N/A
	55**	Female	1.0	19.5	N/A	N/A	N/A	N/A	N/A	N/A
Albafix ECO, High Concentration, Solution 6 (Autoclaved) Test IP	56	Female	1.0	20.0	N/A	N/A	N/A	N/A	3 A, 13A	None
	57	Female	0.9	17.1	N/A	N/A	N/A	N/A	3 A, 13A	None
	58	Female	1.0	19.9	N/A	N/A	N/A	N/A	3 A, 13A	None
	59	Female	1.1	21.2	N/A	N/A	N/A	N/A	3 A, 13A	None
	60	Female	1.1	21.2	N/A	N/A	N/A	N/A	3 A, 13A	None
Albafix ECO, Low Concentration, Solution 7 Test IV	61	Female	1.1	21.1	N/A	N/A	N/A	N/A	13A	None
	62	Female	1.0	19.2	N/A	N/A	N/A	N/A	13A	None
	63	Female	1.1	22.8	N/A	N/A	N/A	N/A	13A	None
	64**	Female	0.9	17.8	N/A	N/A	N/A	N/A	N/A	N/A
	65**	Female	1.1	22.3	N/A	N/A	N/A	N/A	N/A	N/A
Albafix ECO, Low Concentration, Solution 7 Test IP	66	Female	1.2	23.0	N/A	N/A	N/A	N/A	3 A, 13A	None
	67	Female	1.1	21.8	N/A	N/A	N/A	N/A	3 A, 13A	None
	68	Female	0.9	17.2	N/A	N/A	N/A	N/A	3 A, 13A	None
	69	Female	1.1	22.1	N/A	N/A	N/A	N/A	3 A, 13A	None
	70	Female	1.0	20.3	N/A	N/A	N/A	N/A	3 A, 13A	None
Albafix ECO, Low Concentration, Solution 8 (Autoclaved) Test IV	71	Female	1.0	20.5	N/A	N/A	N/A	N/A	13A	None
	72	Female	1.1	21.5	N/A	N/A	N/A	N/A	13A	None
	73	Female	1.1	22.3	N/A	N/A	N/A	N/A	13A	None
	74**	Female	0.9	18.8	N/A	N/A	N/A	N/A	N/A	N/A
	75**	Female	1.1	22.4	N/A	N/A	N/A	N/A	N/A	N/A
Albafix ECO, Low Concentration, Solution 8 (Autoclaved) Test IP	76	Female	1.1	22.3	N/A	N/A	N/A	N/A	3 A, 13A	None
	77	Female	1.1	21.9	N/A	N/A	N/A	N/A	3 A, 13A	None
	78	Female	1.1	22.0	N/A	N/A	N/A	N/A	3 A, 13A	None
	79	Female	0.9	17.8	N/A	N/A	N/A	N/A	3 A, 13A	None
	80	Female	1.1	21.9	N/A	N/A	N/A	N/A	3 A, 13A	None

* Summary of clinical observations, Immediately, 4, 24, 48, and 72 h after injection.

- 3A Clonic convulsions
- 2C Animals unresponsive for approximately 1 min then appeared drowsy until gently prodded.
- 13A Observed Death

** Animals not dosed due to immediate death of first three animals in group.

TABLE 1
Animal Weights and Clinical Observations (Cont.)

Group	Animal #	Sex	Dose (mL)	Body Weight (g)				Weight Change	Signs of Toxicity*
				Day 0 07/06/10	Day 1 07/07/10	Day 2 07/08/10	Day 3 07/09/10		
NaCl Control 50 mL/kg Test IV	81	Female	1.0	20.6	21.0	21.7	22.2	1.6	None
	82	Female	0.9	18.5	19.1	19.7	20.2	1.7	None
	83	Female	1.1	22.5	23.8	24.8	25.5	3.0	None
	84	Female	0.9	17.8	18.7	19.7	20.2	2.4	None
	85	Female	0.9	18.3	18.9	19.8	20.5	2.2	None
NaCl Control 50 mL/kg Test IP	86	Female	1.1	21.2	21.9	22.3	23.7	2.5	None
	87	Female	1.0	20.3	21.4	22.0	22.4	2.1	None
	88	Female	1.0	19.2	20.3	21.3	22.7	3.5	None
	89	Female	0.9	17.0	18.1	18.5	19.6	2.6	None
	90	Female	1.1	22.1	23.0	23.9	24.3	2.2	None

* Summary of clinical observations, immediately, 4, 24, 48, and 72 h after injection.

Table 2

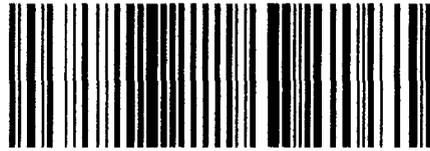
Solution	pH	Adjusted pH
Albafix ECO, High Concentration, Solution 5	7.3	*
Albafix ECO, High Concentration, Solution 6 (Autoclaved)	7.9	*
Albafix ECO, Low Concentration, Solution 7	7.2	*
Albafix ECO, Low Concentration, Solution 8 (Autoclaved)	7.8	*

*Dosed as received

High concentration: 142.0 mg/kg

Low concentration: 79.5 mg/kg

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