



CONSUMER PRODUCT
TESTING COMPANY

cptlab.com

FDA Registration# 1000151293
DEA Registration# RC0189144 Schedule I-V
US EPA/NH DEP Registration# NID982726648
ISO/IEC 17025:2005 Accredited

QUALITY ASSURANCE UNIT STATEMENT

Study No.: V18-3901

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies. This study has been performed under Good Laboratory Practice principles (including government regulations to the extent applicable) and in accordance with standard operating procedures and applicable standard protocols. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date listed below. The findings of this inspection may have been reported to management and the Study Director.

Date of data inspection:

7/9/18

Quality Assurance:

 7/11/18

Signature/Date

FINAL REPORT


CLIENT: Argaman Technologies Ltd
6 Harashei Barzel Street
Jerusalem, 9342130
Israel

ATTENTION: Gohar Kazarian

TEST: The Hen's Egg Test - Utilizing the Chorioallantoic Membrane (HET-CAM)

TEST ARTICLE: Fabric CTXSC55 FK18-001, CottonX™ Skincare Cosmetic Fabric, Knit Jersey color beige: Active ingredient: CottonX™ Skincare fibers composed of natural cotton fibers $\leq 25\%$ (by weight) impregnated with Argo9825 (EPA Reg Number: 91367-1), Lot number: 2

EXPERIMENT REFERENCE NO.: V18-3901


Steven Nitka
Vice President
Laboratory Director



FDA Registration# 1000151293
DEA Registration# RCO199744 Schedule I-V
US EPA/NJ DEP Registration# NJD982726648
ISO/IEC 17025:2005 Accredited

Office: +1 (973) 808-7111 Fax: +1 (973) 808-7234 70 New Dutch Lane Fairfield, NJ 07004-2514

Clinical • Photobiology • Analytical Chemistry • Microbiology • In-Vitro Safety • Consulting

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without authorization.

Objective:

To evaluate the test article for irritancy potential utilizing the HET-CAM test. The test is a modification of that described by Kemper and Luepke.¹

Introduction:

The chick embryo has been used extensively in toxicology. "The chorioallantoic membrane (CAM) of the chick embryo is a complete tissue with organoid elements from all germ cell layers. The chorionic epithelium is ectodermal and the allantoic epithelium is endodermal. The mesoderm located between these epithelia is a complete connective tissue including arteries, capillaries, veins and lymphatic vessels. The CAM responds to injury with a complete inflammatory reaction, comparable to that induced in the rabbit eye test. It is technically easy to study, and is without nerves to sense pain."²

Test Article: Fabric CTXSC55 FK18-001, CottonX™ Skincare Cosmetic Fabric, Knit Jersey color beige: Active ingredient: CottonX™ Skincare fibers composed of natural cotton fibers ≤25% (by weight) impregnated with Argo9825 (EPA Reg Number: 91367-1), Lot number: 2

Reference Articles: Johnson's Baby Powder
Sodium Lauryl Sulfate

Date of Assay: June 29, 2018

¹Kemper, F.H. & Luepke, N.P., (1986). The HET-CAM Test: An Alternative to the Draize Test. *FD Chem. Toxic.* 24, p. 495 - 496.

²Leighton, J., Tchao, R., Verdone, J. & Nassauer, J. Macroscopic Assay of Focal Injury in the Chorioallantoic Membrane. In: *Alternative Methods in Toxicology*, Vol. 3, *In Vitro Toxicology E2*, pp. 357 - 369, Alan M. Goldberg, (ed.), Mary Ann Liebert Publishers, Inc., New York, 1985.

Method:

White Leghorn eggs were obtained from Moyer's Chicks, Inc., in Quakertown, Pennsylvania. For incubation at this facility, the eggs were placed in a Kuhl, humidified incubator. The incubator is such that the eggs are automatically rotated once every hour. The temperature was controlled at 37° C (\pm 2° C). On day eight (8) the eggs were turned so that the acutely angled end faced down.

On day ten (10) each egg was removed from the incubator and placed in a Plexiglas work enclosure. This enclosure had been preheated and humidified so that its environment approached that of the incubator. A cut was made in the larger end of each egg, where the air sack is located. A Dremel® Moto-Flex Tool (model 232-5) equipped with a Dremel® Cut-Off Wheel (No. 409) was used to make each cut. Forceps were then used to remove the shell down to the shell-membrane junction. The inner egg membrane was then hydrated with a warm, physiological saline solution. The saline was removed after a two (2) to five (5) minute exposure. Utilizing pointed forceps, the inner egg membrane was then carefully removed to reveal the CAM.

The test article, at a dosage of one (1) square centimeter (moistened with saline), was then administered to each of four (4) CAM's. Twenty seconds later, the test article was rinsed from each CAM with five (5) milliliters of physiological saline. All CAM's were observed immediately prior to test article administration and at 30 seconds, two and five minutes after exposure to the test article. Photographs of each egg were taken at each interval including pre-dosing. The reactions of the CAM, the blood vessels, including the capillaries, and the albumin were examined and scored for irritant effects as detailed below:

Effect	Time (min.)	Score		
		0.5	2	5
Hyperemia		5	3	1
Minimal Hemorrhage ("Feathering")		7	5	3
Hemorrhage (Obvious Leakage)		9	7	5
Coagulation and/or Thrombosis		11	9	7

The numerical, time dependent scores were totaled for each CAM. Each reaction type can be recorded only once for each CAM, therefore the maximum score per CAM is 32. The mean score was determined for all CAM's similarly tested.

Results:

Test Article (%)	CAM #	Scores @			
		0.5 min.	2 min.	5 min.	Total
Fabric CTXSC55 FK18-001,	1	0	0	1	1
CottonX(TM) Skincare Cosmetic	2	0	3	0	3
Fabric, Knit Jersey color beige:	3	0	0	0	0
Active ingredient: CottonX(TM)	4	0	0	0	0
Skincare fibers composed of*				Average:	1.00

Reference Article (%)	CAM #	Scores @			
		0.5 min.	2 min.	5 min.	Total
Johnson's Baby	1	5	0	0	5
Powder (100%)	2	0	3	0	3
	3	0	3	0	3
	4	0	3	0	3
				Average:	3.50

Reference Article (%)	CAM #	Scores @			
		0.5 min.	2 min.	5 min.	Total
Sodium Lauryl Sulfate (100%)	1	5 7 11	0	0	23
	2	5 7	9	0	21
	3	5 7	0	7	19
	4	5 7	7 9	0	28
				Average:	22.75

Each article was then classified as indicated in the following:

Mean Score	Irritation Potential
0.0 - 4.9	Practically none
5.0 - 9.9	Slight
10.0 - 14.9	Moderate
15.0 - 32.0	Severe

*natural cotton fibers <25% (by weight) impregnated with Argo9825 (EPA Reg Number: 91367-1), Lot number: 2 (100%)

Objective:

To evaluate the test article for irritancy potential utilizing the HET-CAM test. The test is a modification of that described by Kemper and Luepke.¹

Introduction:

The chick embryo has been used extensively in toxicology. "The chorioallantoic membrane (CAM) of the chick embryo is a complete tissue with organoid elements from all germ cell layers. The chorionic epithelium is ectodermal and the allantoic epithelium is endodermal. The mesoderm located between these epithelia is a complete connective tissue including arteries, capillaries, veins and lymphatic vessels. The CAM responds to injury with a complete inflammatory reaction, comparable to that induced in the rabbit eye test. It is technically easy to study, and is without nerves to sense pain."²

Test Article: Fabric CTXSC55 FK18-001, CottonX™ Skincare Cosmetic Fabric, Knit Jersey color beige: Active ingredient: CottonX™ Skincare fibers composed of natural cotton fibers ≤25% (by weight) impregnated with Argo9825 (EPA Reg Number: 91367-1), Lot number: 2

Reference Articles: Johnson's Baby Powder
Sodium Lauryl Sulfate

Date of Assay: June 29, 2018

¹Kemper, F.H. & Luepke, N.P., (1986). The HET-CAM Test: An Alternative to the Draize Test. *FD Chem. Toxic.* 24, p. 495 - 496.

²Leighton, J., Tchao, R., Verdone, J. & Nassauer, J. Macroscopic Assay of Focal Injury in the Chorioallantoic Membrane. In: *Alternative Methods in Toxicology*, Vol. 3, *In Vitro Toxicology E2*, pp. 357 - 369, Alan M. Goldberg, (ed.), Mary Ann Liebert Publishers, Inc., New York, 1985.

Method:

White Leghorn eggs were obtained from Moyer's Chicks, Inc., in Quakertown, Pennsylvania. For incubation at this facility, the eggs were placed in a Kuhl, humidified incubator. The incubator is such that the eggs are automatically rotated once every hour. The temperature was controlled at 37° C (\pm 2° C). On day eight (8) the eggs were turned so that the acutely angled end faced down.

On day ten (10) each egg was removed from the incubator and placed in a Plexiglas work enclosure. This enclosure had been preheated and humidified so that its environment approached that of the incubator. A cut was made in the larger end of each egg, where the air sack is located. A Dremel[®] Moto-Flex Tool (model 232-5) equipped with a Dremel[®] Cut-Off Wheel (No. 409) was used to make each cut. Forceps were then used to remove the shell down to the shell-membrane junction. The inner egg membrane was then hydrated with a warm, physiological saline solution. The saline was removed after a two (2) to five (5) minute exposure. Utilizing pointed forceps, the inner egg membrane was then carefully removed to reveal the CAM.

The test article, at a dosage of one (1) square centimeter (moistened with saline), was then administered to each of four (4) CAM's. Twenty seconds later, the test article was rinsed from each CAM with five (5) milliliters of physiological saline. All CAM's were observed immediately prior to test article administration and at 30 seconds, two and five minutes after exposure to the test article. Photographs of each egg were taken at each interval including pre-dosing. The reactions of the CAM, the blood vessels, including the capillaries, and the albumin were examined and scored for irritant effects as detailed below:

Effect	Time (min.)	Score		
		0.5	2	5
Hyperemia		5	3	1
Minimal Hemorrhage ("Feathering")		7	5	3
Hemorrhage (Obvious Leakage)		9	7	5
Coagulation and/or Thrombosis		11	9	7

The numerical, time dependent scores were totaled for each CAM. Each reaction type can be recorded only once for each CAM, therefore the maximum score per CAM is 32. The mean score was determined for all CAM's similarly tested.

Results:

Test Article (%)	CAM #	Scores @			
		0.5 min.	2 min.	5 min.	Total
Fabric CTXSC55 FK18-001,	1	0	0	1	1
CottonX(TM) Skincare Cosmetic	2	0	3	0	3
Fabric, Knit Jersey color beige:	3	0	0	0	0
Active ingredient: CottonX(TM)	4	0	0	0	0
Skincare fibers composed of*				Average:	1.00

Reference Article (%)	CAM #	Scores @			
		0.5 min.	2 min.	5 min.	Total
Johnson's Baby	1	5	0	0	5
Powder (100%)	2	0	3	0	3
	3	0	3	0	3
	4	0	3	0	3
				Average:	3.50

Reference Article (%)	CAM #	Scores @			
		0.5 min.	2 min.	5 min.	Total
Sodium Lauryl Sulfate (100%)	1	5 7 11	0	0	23
	2	5 7	9	0	21
	3	5 7	0	7	19
	4	5 7	7 9	0	28
				Average:	22.75

Each article was then classified as indicated in the following:

Mean Score	Irritation Potential
0.0 - 4.9	Practically none
5.0 - 9.9	Slight
10.0 - 14.9	Moderate
15.0 - 32.0	Severe

*natural cotton fibers <25% (by weight) impregnated with Argo9825 (EPA Reg Number: 91367-1), Lot number: 2 (100%)

Discussion:

Previous studies have shown that the CAM of the hen's egg is more sensitive to liquid irritants than is the rabbit eye. Therefore, the solid test and reference articles were used as received.

Historical *In Vivo* Results:

The Johnson's reference product has historically been categorized as being practically non-irritating, eliciting scores approaching 0, at 24 hours, when dosed at 100% and tested using the Draize ocular irritation methodologies (Draize Scale: 0 – 110). The Sodium Lauryl Sulfate reference product has historically been categorized as being severely irritating, eliciting scores approaching 30, at 24 hours, when dosed at 100% and tested using the Draize ocular irritation methodologies.

Conclusion:

Under the conditions of this test, the results indicate that the sponsor-submitted product, Fabric CTXSC55 FK18-001, CottonX™ Skincare Cosmetic Fabric, Knit Jersey color beige: Active ingredient: CottonX™ Skincare fibers composed of natural cotton fibers ≤25% (by weight) impregnated with Argo9825 (EPA Reg Number: 91367-1), Lot number: 2, at 100%, would have practically no ocular irritation potential *in vivo*.

Record Retention:

All records and documents pertaining to the conduct of this study shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QA Department to obtain custody of study records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, study-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Professional personnel involved:

Steven Nitka, B.S.	-	Vice President Laboratory Director (Study Director)
Lillian Vazquez, B.S.	-	Laboratory Supervisor
Christine Vornehm	-	Quality Assurance Compliance Specialist
William Cavaliere	-	Quality Assurance Supervisor