Consumer Product Testing Co.

EST. 1975

FINAL REPORT

CLIENT:

Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road
West District of Shenze Industrial Base
Shen Ze County, Hebei Province 050000
China

AUTHORIZING AGENT: Kathy Liu

TESTS:

Primary Dermal Irritation in Rabbits
Guinea Pig Sensitization (Buehler)

TEST ARTICLE:

Powder Free Nitrile Patient Examination Gloves,
Blue Lot#: 0912C4A3-PF

EXPERIMENT REFERENCE NUMBER: T10-0949

5/7/10

Steven Nitka
Vice President
Laboratory Director

70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234

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QUALITY ASSURANCE UNIT STATEMENT

Study No.: T10-0949

The objective of the Quality Unit (QU) is to monitor the conduct and accurate reporting of non-clinical laboratory studies. This study has been performed under Good Laboratory Practice Regulations (21 CFR Part 58) and in accordance with CPTC Standard Operating Procedures (SOP's) and applicable standard protocols. The QU maintains copies of study protocols and SOP's and has inspected this study on the date(s) indicated below. The findings of these inspections have been reported to CPTC Management and the Study Director.

Date(s) of inspection(s): 03/17/10, 03/31/10, 04/27/10, 05/05/10

Date(s) finding(s) reported to CPTC Management and the Study Director: 04/05/10, 05/03/10

Quality Unit Certified By: Christine Hendrick Date: 5/7/10

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Clinical • Toxicology • Analytical Chemistry • Microbiology

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Final Report Summary

CLIENT: Better Care Plastic Technology Co., Ltd.
STUDY NO.: T10-0949
REFERENCE: K. Liu
TEST ARTICLE: Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF
TEST ARTICLE RECEIPT DATE: February 25, 2010
EXPERIMENTAL INTERVAL: April 27, 2010 to April 30, 2010

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand White rabbits each received a single dermal application of approximately one (1) square inch of the test article on each of two (2) test sites, one (1) abraded and one (1) non-abraded. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. Each dosage was moistened with saline and applied so that the inside surface of the glove contacted the skin of the test sites of ½ of the animals and the outside surface of the glove contacted the skin of the test sites of the remaining ½ of the animals.

Results: Primary Irritation Index: 0.80

Conclusion: According to Federal Hazardous Substances Act Regulations (16 CFR 1500.41), and under the conditions of this test, this test article is not a primary dermal irritant.

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Final Report Summary

CLIENT: Better Care Plastic Technology Co., Ltd.
STUDY NO.: T10-0949
REFERENCE: K. Liu
TEST ARTICLE: Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF
TEST ARTICLE RECEIPT DATE: February 25, 2010
EXPERIMENTAL INTERVAL: March 31, 2010 to April 30, 2010

Guinea Pig Sensitization (Buehler)

Method: Twelve (6M:6F) Hartley albino, outbred, viral antibody free, guinea pigs (SPF Hartley guinea pig Aai: (HA) Outbred), 364 - 426 grams, each received three (3) topical, occluded applications of the test article during the induction period of three (3) weeks. An additional group of ten (5M:5F) Hartley-strain guinea pigs, 364 - 419 grams, served as a control group. These animals did not receive induction applications. Fourteen days after the last induction application, the animals in the test group received a topical application of the test article to a dorsal, virgin site. At the same time, the control group animals received an identical dosage of the test article. Observations of irritation and other effects were recorded 7 and 24 hours after each induction application and 7, 24 and 48 hours following the challenge application. Each dosage (one (1) square inch) was moistened with saline and applied so that the inside surface of the glove contacted the skin of the test sites of ½ of the animals and the outside surface of the glove contacted the skin of the test sites of the remaining ½ of the animals.

Results:

	Challenge	
Index:	Incidence	Severity
Group	Test/Control	Test/Control
Scoring Interval:		
7 Hours:	0.00/0.00	0.00/0.00
24 Hours:	0.00/0.00	0.00/0.00
48 Hours:	0.00/0.00	0.00/0.00

Conclusion: This test article is not a sensitizer in guinea pigs, under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score, divided by the number of animals observed, at challenge.
Severity Index = The sum of the erythema scores, divided by the number of animals observed, at challenge.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand White rabbits, weighing approximately two (2) kilograms and about three (3) months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated for 13 days prior to test initiation. They were individually housed in stainless steel cages, in a room with a 12 hour light/dark cycle. The room temperature was controlled to comply with Animal Welfare Regulations with an approximate range of 65° to 75° F. The humidity was also monitored. Diet consisted of Lab Diet Certified Rabbit Diet #5322 @ 100 g/day/animal, as well as water, *ad libitum*. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were re-examined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close clipping the hair of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using an Oster® small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in restrainers. Two (2) test sites, each two and one-half (2.5) centimeters by two and one-half (2.5) centimeters, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one (1) square inch of the test article was made to each pre-moistened test site. The test article was applied so that the inside surface of the glove contacted the skin of the test sites of ½ of the animals and the outside surface of the glove contacted the skin of the test sites of the remaining ½ of the animals. It was then covered with a square, surgical gauze pad, five (5) centimeters on each side and a Kendall Webril® pad. The latter was held in place with three (3) inch 3M Micropore™ tape.

[1]J.H. Draize, "Dermal Toxicity", *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics*, (The Association of Food and Drug Officials of the United States, 1959), p. 47.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable plastic occlusive wrapping fixed in place with three (3) inch 3M Micropore™ tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently washed from the skin with water and paper towels. Each test site was individually examined and scored at 24 and 72 hours, for erythema and edema, using the Draize skin scoring scale (refer to the appended table). The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for the 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of five (5) or more indicates a primary dermal irritant.

Characterization of the test article was not performed by this facility. All materials and data pertinent to this study will be stored in the archive facilities utilized by Consumer Product Testing Company.

Guinea Pig Sensitization (Buehler)

This test was designed to determine if the test article is a potential sensitizer to guinea pigs when applied topically. The method is essentially that described by Buehler.[1,2]

Hartley albino, outbred, viral antibody free, guinea pigs (SPF Hartley guinea pig Aai: (HA) Outbred), male and female, were used for this test. The animals were obtained through Elm Hill in Chelmsford, Massachusetts. They were carefully checked upon receipt and prior to test initiation for evidence of poor health. They were housed in stainless steel cages in a temperature controlled room with a 12 hour light/dark cycle. The room temperature was controlled to comply with Animal Welfare Regulations with an approximate range of 65° to 75° F. The humidity was also monitored. The animals were identified through individual markings, as well as cage labels. Diet consisted of Lab Diet Certified Guinea Pig Diet #5026, as well as water, *ad libitum*. The animals were acclimated for seven (7) days prior to test initiation.

For induction, twelve (6M:6F) guinea pigs, (test group), were prepared by shaving site 1 with an Oster® small animal clipper equipped with a #40 (surgical) head. One (1) square inch of the test article was moistened with saline and applied to site 1 of each animal, under an occluded patch, consisting of a 25 mm Hilltop Chamber with a cotton patch and a piece of three (3) inch Tensoplast® tape (BSN medical S.A.S., Vibraye, France) lined on the adhesive side with a three and one-half (3.5) inch wide strip of Hygenic® Dental Dam. The test article was applied so that the inside surface of the glove contacted the skin of the test sites of ½ of the animals and the outside surface of the glove contacted the skin of the test sites of the remaining ½ of the animals. The test sites were scored, seven (7) and 24 hours after application, for irritation. Applications were made once a week for three (3) consecutive weeks. An additional ten (5M:5F) animals were carried through the induction phase as a control. They were not exposed to the test article until challenge.

Fourteen days after the third induction application, a challenge application was made to site 3 on the test and the control group animals. The wraps were applied and removed as previously stated. The sites were scored 7, 24 and 48 hours after application.

[1]E.V. Buehler, "Delayed Contact Hypersensitivity in the Guinea Pig," *Arch Derma*, 91, (1965), pp. 171 - 175.

[2]H.L. Ritz & E.V. Buehler, "Planning, Conduct and Interpretation of Guinea Pig Sensitization Patch Tests," *Current Concepts in Cutaneous Toxicity*, V.A. Drill and P. Lazar, (Eds.), Academic Press, (1980), pp. 25 - 41.

Two (2) indices were calculated from the challenge irritation scores, one (1) to evaluate the incidence of irritation (reaction) and the other to evaluate the severity of irritation. The indices for incidence and severity were calculated for both groups from all three (3) scoring intervals. The incidence index was calculated by counting the number of animals showing an irritation response (1 or greater), for a specified time period and by dividing that number by the number of test sites (animals) examined at that time period (# responses/# per group). The severity index was calculated by adding the irritation scores for a specified time period and dividing that sum by the number of animals observed (sum of irritation scores/# animals observed). The two (2) indices were used to evaluate the sensitization potential of the test article.

All animals appeared healthy throughout the study and all gained weight. Initial and terminal body weights were recorded for all animals.

This facility will also be reporting the results of a positive control test conducted within six (6) months of this test.

Characterization of the test article was not performed by this facility. All materials and data pertinent to this study will be stored in the archive facilities utilized by Consumer Product Testing Company.

Primary Dermal Irritation in Rabbits

The scoring scale used is presented in Table 1. The individual test results are presented in Table 2.

Guinea Pig Sensitization (Buehler)

The scoring scale used is presented in Table 3. The test site configuration is presented in Figure 1. Individual test and control group results are presented in Tables 4 and 5 respectively.

Professional personnel involved:

Steven Nitka, B.S.	-	Vice President Laboratory Director (Study Director)
Lillian Vazquez, B.S.	-	Laboratory Supervisor
Christine Hendricks	-	Quality Assurance Group Leader

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

ERYTHEMA FORMATION	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score = 4	

EDEMA FORMATION	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (area raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score = 4	

Total possible primary irritation score = 8

Table 2

Primary Dermal Irritation in Rabbits
Individual Results

Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF

Dose: 1 sq" TA moist with saline *Date: 04/27/10*

Rabbit Number & Sex	Skin	24 Hours ER / ED	72 Hours ER / ED
1 (22) M	INTACT	1 / 0	1 / 0 D S
	ABRADED	2 / 0	2 / 1 D S
2 (23) F	INTACT	0 / 0	0 / 0
	ABRADED	1 / 0	1 / 0
3 (24) M	INTACT	0 / 0	0 / 0
	ABRADED	1 / 0	1 / 0
4 (25) F	INTACT	0 / 0	0 / 0
	ABRADED	0 / 0	0 / 0
5 (26) M	INTACT	0 / 0	0 / 0
	ABRADED	1 / 0	2 / 0
6 (27) F	INTACT	0 / 0	0 / 0
	ABRADED	2 / 0	2 / 1

Combined Sum of Means: 3.2
Primary Irritation Index: 0.80

Raw Data Page: 157515
ER/ED = Erythema and Edema Scores
D = Dry
S = Scaling

The inside of the gloves contacted the skin of animals #1-3, and the outside surface of the gloves contacted the skin of animals #4-6.

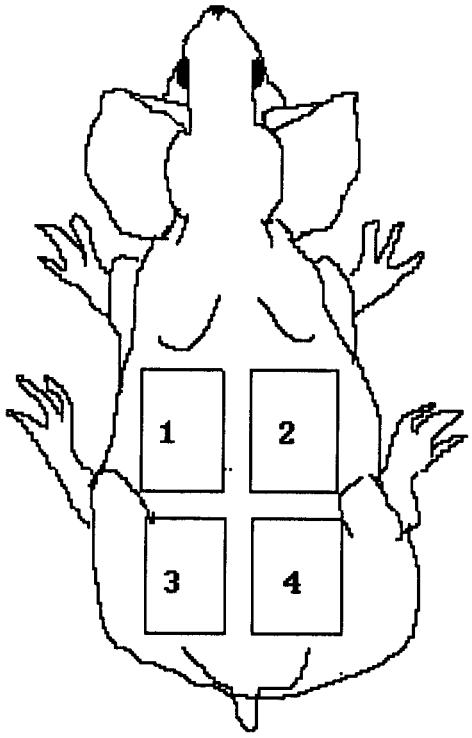
Table 3

Scoring Criteria for Skin Reactions

Value	Definition
0	No reaction
±	Very faint erythema, usually nonconfluent
1	Faint erythema, usually confluent
2	Moderate erythema
3	Strong erythema, with or without edema

FIGURE 1

GUINEA PIG SENSITIZATION



APPLICATION SITES

Table 4

GUINEA PIG SENSITIZATION (BUEHLER)

INDIVIDUAL RESULTS

Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF

Test Group

Dosage: 1 square inch Test Article using 25 mm Hilltop Chamber moist with saline

	Time After Application	Animal Number/Sex 1M	2M	3M	4M	5M	6M
Initial Bdwts. (grams):		401	408	394	392	426	398
Induction							
1	7 Hours	0	0	0	0	0	0
	24 Hours	0	0	0	0	0	0
2	7 Hours	0	0	0	0	±	0
	24 Hours	0	0	0	0	0	0
3	7 Hours	0	0	1	0	0	0
	24 Hours	0	0	0	0	0	0
Challenge	7 Hours	0	0	0	0	0	0
	24 Hours	0	0	0	0	0	0
	48 Hours	0	0	0	0	0	0
Terminal Bdwts. (grams):		652	669	632	589	670	604

Raw Data Page: 157465

The inside surface of the gloves contacted the skin of animals #1-3, and the outside surface of the gloves contacted the skin of animals #4-6.

Table 4
(continued)

GUINEA PIG SENSITIZATION (BUEHLER)

INDIVIDUAL RESULTS

Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF

Test Group

Dosage: 1 square inch Test Article using 25 mm Hilltop Chamber moist with saline

	Time After Application	Animal Number/Sex 7F	8F	9F	10F	11F	12F
Initial Bdwts. (grams):		374	426	378	402	379	364
Induction							
1	7 Hours	0	0	0	0	0	0
	24 Hours	0	0	0	0	0	0
2	7 Hours	0	0	±	0	0	0
	24 Hours	0	0	0	0	0	0
3	7 Hours	0	0	0	0	0	±
	24 Hours	0	0	0	0	0	0
Challenge	7 Hours	0	0	0	0	0	0
	24 Hours	0	0	0	0	0	0
	48 Hours	0	0	0	0	0	0
Terminal Bdwts. (grams):		549	574	587	572	574	560

Raw Data Page: 157465

The inside surface of the gloves contacted the skin of animals #7-9, and the outside surface of the gloves contacted the skin of animals #10-12.

Table 5

GUINEA PIG SENSITIZATION (BUEHLER)

INDIVIDUAL RESULTS

Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF

Control Group

Dosage: 1 square inch Test Article using 25 mm Hilltop Chamber moist with saline

	Time After Application	----------Animal Number/Sex---------- 1M	2M	3M	4M	5M
Initial Bdwts. (grams):		388	419	392	397	397
Challenge	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		632	642	628	598	592

Raw Data Page: 157466

The inside surface of the gloves contacted the skin of animals #1-3, and the outside surface of the gloves contacted the skin of animals #4-5.

Table 5
(continued)

GUINEA PIG SENSITIZATION (BUEHLER)

INDIVIDUAL RESULTS

Powder Free Nitrile Patient Examination Gloves, Blue Lot#: 0912C4A3-PF

Control Group

Dosage: 1 square inch Test Article using 25 mm Hilltop Chamber moist with saline

	Time After Application	Animal Number/Sex 6F	7F	8F	9F	10F
Initial Bdwts. (grams):		374	364	369	379	369
Challenge	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		517	574	549	613	525

Raw Data Page: 157466

The inside surface of the gloves contacted the skin of animals #6-7, and the outside surface of the gloves contacted the skin of animals #8-10.