확인	작성자	검토자	SD	QAU
서 명				
일 자				

Final report

MGK-2023-000526

Kinesiology tape

Skin sensitization test (Buehler test) of the Kinesiology tape in guinea pig

KOREA TESTING & RESEARCH INSTITUTE

Kwon Oh-jung

Final report

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GLP Statement

Study title : Skin sensitization test (Buehler test) of the Kinesiology tape in guinea pig

Study number : MGK-2023-0[redacted]

Sponsor

Name	: [redacted]
Address	: Pusan National University Hyowon Industry-Academic Cooperation Buling Room 308, 2, Busandaehak-ro 63beon-gil, Geumjeong-gu, Busan, Republic of Korea
Representative	: Choi seoung won
Person in charge	: Woo chang Kwon
Department and position	: R&D / General manager
Contact Number	: Tel. [redacted] Fax. [redacted]

Test facility

Name	: Korea Testing and Research Institute, Hwasun
Address	: 12-63, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Republic of Korea
Test facility management	: Lee Seung-young
Contact number	: Tel. +82-61-370-7700 Fax. +82-61-370-7777

This study was conducted under the supervision of the study director in compliance with the principles of Good Laboratory Practice.

1. Good Laboratory Practice (GLP)

1.1. Notice of Ministry of Food and Drug Safety No.2022-93(2022-12-27), Good Laboratory Practice

1.2. OECD "Principles of Good Laboratory Practice, ENV/MC/CHEM (98)17 (as revised in 1997)"

2. Test regulation

2.1 ISO 10993-10 : 2021, Tests for skin sensitization

This study was performed by study plan, and the report provides a true and accurate record of the results obtained.

Study director _____ _____

Jung Ja-kyun, M.S. Date

Test facility management _____ _____

Lee Seung-young, M.S. Date

Quality Assurance Statement

Study title : Skin sensitization test (Buehler test) of the Kinesiology tape in guinea pig

Study number : MGK-2023-0[redacted]

Study Phases	Inspections	Reports to study director & Reports to management
Study plan audit		
Animal receipt audit		
Group assignment audit		
Test sample preparation audit		
Induction phase audit		
Challenge phase audit		
Skin reaction observation audit		
Raw data audit		
Final report (Draft) audit		
Final report audit		

Inspections of the routine and repetitive procedures that constitute the study were carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress.

This report has been audited by KTR Quality Assurance Unit, and is considered to be an accurate account of the raw data generated and of the procedures followed.

Inspections were accomplished as noted, and reported to the study director and management immediately following their completion. Based on these inspections and the review of the report, this study was conducted and reported in conformance with the Good Laboratory Practice regulations.

Quality assurance personnel Choi Min-seok, M.S. Date

Study Staffs

The staffs who conducted this study in compliance with the KTR Hwasun SOPs and the study plan were as follows.

Study personnel	: Cho Yun-sung
	Lee Eun-young
	Lee Sang-yul
	Noh Moon-young
	Jung Ja-kyun
	Jung Jeong-uk
	Jung Yong-jin
	Park Shin-hwa
	Shin Ho-jin
	Seo Joon-young
	Sung Woo-jin
	Yoon Jeong-gwon
Director of test sample management	: Park Shin-hwa
Animal care manager	: Lee Taek-jin
Report writing	: Noh Moon-young

Contents

1. Summary

The purpose of this study was to investigate the skin sensitizing potency of the Kinesiology tape using the Buehler test.

The clinical signs, mortality, body weight changes and skin response were evaluated as follows.

- As an observation of the clinical sign during the test period, specific clinical signs and dead animals were not observed.
- As a measurement of body weight during the test period, body weight changes by applying the test sample were not observed.
- The sensitization score and rate were calculated as 0.0, 0.0 % and 0.0, 0.0 % in G2 (polar vehicle test group) at 24 h and 48 h after the challenge.

In these results, the Kinesiology tape was considered to have no skin sensitization potency as skin reactions were not observed in the evaluation by Buehler test.

2. Introduction

The purpose of this study was to evaluate the skin sensitization for the Kinesiology tape in guinea pig.

2.1 Animal welfare

- Animal Protection Act. No. 19486 (2023-06-20, partial amendment)
- Laboratory Animal Act. No. 18853 (2022-04-26, Amendment by Other Act)
- Approval number of Institutional Animal Care and Use Committee : IAC2023-1926

2.2 Study schedule

Study initiation date	: 2023-06-21
Experimental starting date	: 2023-06-22
Animal receipt date	: 2023-06-22
acclimation period	: 2023-06-22 - 2023-06-26
Group assignment date	: 2023-06-26
Induction phase date	: 2023-06-27, 2023-06-28, 2023-06-29, 2023-07-03, 2023-07-04, 2023-07-05, 2023-07-10, 2023-07-11, 2023-07-12
Challenge phase date	: 2023-07-26
Skin reaction observation date	: 2023-07-27, 2023-07-28
Experimental completion date	: 2023-07-28
Final report (Draft) preparation date	: 2023-08-11
Study completion date	: Signature date (Study Director)

3. Materials & Preparation

3.1 Test sample (Annex 1, 2)

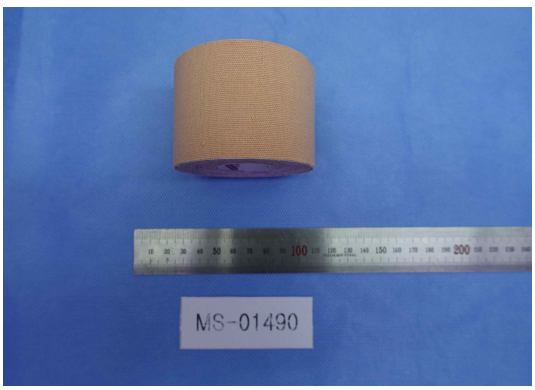
Test sample name	: Kinesiology tape
Item name	: Kinesiology tape
Model name	: B Balance tape
Lot No.	: 230401
Manufacturer	: [redacted]Inc
KTR code	: MS-01490
Expiration date	: N.A.
Appearance	: 5 cm x 5 m roll type Cotton or silk or Hemp B balance tape are suitable for taping any part of the body. They are made of high quality eco-cotton and do not contain latex, which eliminates the occurrence of allergic reactions. The high breathability of the tape allows your skin to breathe freely, so that it does not get stuck under the tape.
Storage condition	: Room temperature (1 - 30) ℃

3.2 Negative control

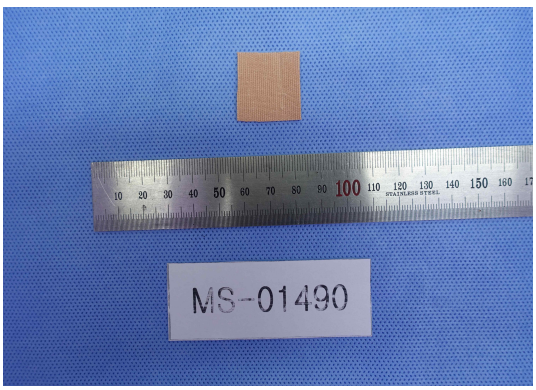
Name	Manufacturer	Lot No.	Storage conditions
Sterile saline	[redacted]Co., Ltd., Korea	76XBB58	Room temperature (1 - 30) ℃

3.3 Preparation of the test sample

The test sample provided by the sponsor is cut into 2.5 cm x 2.5 cm pieces and use.



Test sample



Test sample prior to administration

3.4 Analysis of the test sample

Analysis of the concentration, stability and uniformity of the test sample was not performed.

3.5 Test system

Species/strain	: Hartley Guinea Pig(HlaKoat:Ha), SPF
Supplier	: Koatech Co., Ltd. (181-21 Jinwi-ro, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do)
Number, sex and age of animals	: 16 males, 5 weeks
Number, sex, age and body weight range at the time of administration	: 15 males, 6 weeks, (325.05 - 373.59) g

3.5.1 Justification of the test system

The Dunkin Hartley guinea pigs were commonly used for this type of study and with plenty of reference data, it was easy to analyze and evaluate regarding the test results.

3.5.2 Quarantine and acclimation

All animals were examined for quarantine at the time of receipt and acclimatized to the housing conditions. The healthy animals were selected and used for the study based on the general health conditions for 5 days.

3.5.3 Identification and group assignment

The animals were labeled with a permanent marker pen for acclimation days and were individually identified with an animal number, using animal marker after the group assignment. Identification cards were attached to each cage for an individual discrimination. After the acclimation periods, animals were weighed and randomly assigned according to the average body weight and standard deviation.

3.5.4 Remnant animals

Remnant animals were euthanized using CO_2 at group assignment day.

3.6 Housing conditions

3.6.1 Animal room number

Quarantine and acclimation	: Room number 5
Treatment and observation	: Room number 3

3.6.2 Environmental conditions

Temperature	: (18.3 - 21.2) ℃
Relative humidity	: (50.3 - 53.8) % R.H.
Air exchange	: (10 - 20) times/h
Illumination and Light cycle	: (150 - 300) lx, Light 12 h (08:00 - 20:00)
Cage style and size	: Stainless steel wire cage, 540 mm(w) × 610 mm(d) × 200 mm(h) Stainless steel wire cage, 490 mm(w) × 700 mm(d) × 230 mm(h)
Animal per cage	: 5 animals

The temperature and relative humidity were monitored automatically every 30 min by automatic instrument and other conditions were measured periodically by SOPs. As a result of environmental measurements in the animal room, there were no changes that were considered to affect the test.

3.6.3 Food and water

The radiation sterilized diet for Guinea pig [Altromin, Germany] contained ascorbic acid was fed and R/O water was taken ad libitum. The absence of contamination was confirmed with periodical analysis results report of manufacture. The water was periodically analyzed in accordance with the SOPs of Korea Testing and Research Institute, Hwasun. In the feed and water inspection, no factors influencing the test were found.

4. Test method

4.1 Group composition

Group	Sex	Animal number	Induction phase	Challenge phase
G1 (Control)	Male	1101 - 1105	Negative Control	Test sample
G2 (Test)	Male	1201 - 1210	Test sample	Test sample

4.2 Method of administration

4.2.1 Clipping the fur

Fur clipping was carried out at least 2 h prior to each phase. The left upper flank area fur was clipped off during the induction phase and the right upper flank area fur was clipped off before the challenge phase and skin reaction evaluation (24 h, 48 h).

4.2.2 Induction phase

Test sample (0.3 mL) was applied to the left upper flank area by using filter paper (2.5 cm x 2.5 cm) and non-irritant adhesive tape (Tegaderm™, 3M) after application, it was held by using Coban (Coban™, 3M) for (6 ± 0.5) h and the patch was removed. The negative control (0.3 mL) was applied in the same manner. This procedure was performed three days a week for three weeks.

4.2.3 Challenge phase

At 14 days after the completion of the last induction phase, the non-irritant tape (Tegaderm™, 3M) attached with Filter paper (2.5 cm x 2.5 cm) included test samples (right, 0.3 mL). It was attached to right upper flank area of each animal, and held using Coban (Coban™, 3M) for (6 ± 0.5) h.

4.3 Observations

4.3.1 Clinical signs

Clinical signs and the condition in animals were observed daily to figure out mortality throughout the test.

4.3.2 Body weight

The body weight of all the animals were measured on the day of animal receipt, group assignment, first induction week, second induction weeks, third induction weeks and challenge day.

4.3.3 Observation of application site

The skin reaction was evaluated on the application site at (24 ± 2) h and (48 ± 2) h after the removal of the patch. The animals were euthanized using CO_2 after observation.

4.4 Evaluation of the test results

The skin responses were evaluated and graded according to [Magnusson and Kligman scale]. The skin response are evaluated and graded according to Table 2. Magnusson and Kligman grades of 1 or greater in the test group generally indicated sensitization, and provided grades of less than 1 are seen in the control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in the control animals are presumed to be due to sensitization. If the response is equivocal, then the rechallenge is to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animals.

[Magnusson and Kligman scale]

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

4.5 Positive control (Annex 3)

The positive control test was conducted every six months using DNCB in accordance with the ISO 10993-10. The positive control group was observed for erythema and edema, the sensitization score was observed at 1.4 and 1.3, the sensitization rate was calculated at 100 % and 100 % at 24 h and 48 h after the challenge.

5. Amendments and deviations from the study plan

There were no amendments and deviations from the approved study plan.

6. Archives

All records which are created during study period will be archived for 5 years after issuance of Good Laboratory Practice final report. After expiration of the storage period, additional storage or disposal will be determined by SOP of Korea Testing and Research Institute, Hwasun after consultation with the sponsor.

6.1 Storage lists

(1) Records on the study plan
(2) Records and raw data on the test sample
(3) Records and raw data on the test system
(4) Records on the observation and measurement
(5) Records on the communication with sponsors
(6) Records on the final report

6.2 Storage facility

Archive room (Ⅰ) of Korea Testing and Research Institute, Hwasun.
Archive room (Ⅱ) of Korea Testing and Research Institute, Hwasun.

7. Results

7.1 Mortality and Clinical Signs (Table 1)

During the test period, dead animals and clinical signs related to the test sample were not observed.

7.2 Body Weight (Table 2)

As a measurement of body weight during the test period, body weight loss was not observed in all animals.

7.3 Evaluation of the skin response (Table 3)

For the result of skin response at 24 h and 48 h after the challenge, the control and test group did not observed erythema, edema, etc., or any skin reactions.

The sensitization score and rate were calculated as 0.0, 0.0 % and 0.0, 0.0 % in G2 (polar vehicle test group) at 24 h and 48 h after the challenge.

8. Discussion & Conclusion

The purpose of this study was to investigate the skin sensitizing potency of Kinesiology tape. The test sample was treated topical application for induction (three times per week, for 3 weeks) and challenge in Dunkin Hartley guinea pigs. Then, it was evaluated clinical signs, mortality and skin sensitization.

The test sample-related clinical signs and dead animals were not observed during the observation period. Any body weights changes by applying the test sample were not observed.

As a result, any skin reactions were not observed erythema and edema etc., at 24 h and 48 h after the challenge treatment, the sensitization score and rate in test and control groups were calculated as 0.0, 0.0 % in G2.

In these results, the Kinesiology tape was considered to have no skin sensitization potency as skin reactions were not observed in the evaluation by Buehler test.

9. References

- Notice of Ministry of Food and Drug Safety No.2020-12(2020-02-25), Chapter 9: 6. Skin sensitization test
- Notice of Ministry of Food and Drug Safety No.2022-93(2022-12-27), Good Laboratory Practice
- ISO 10993-1 : 2018, Evaluation and testing within a risk management process
- ISO 10993-10 : 2021, Tests for skin sensitization
- ISO 10993-12 : 2021, Sample preparation and reference materials
- OECD "Principles of Good Laboratory Practice, ENV/MC/CHEM (98)17 (as revised in 1997)"

10. Tables

Table 1. Mortality and clinical signs

Group	Number of animals	Mortality	Animal Number	Clinical signs															
			Days	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
G1	5	0/5(0)[a]	1101	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1102	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			Days	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
			1101	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1102	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
G2	10	0/10(0)[a]	Days	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
			1201	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1202	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1203	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1204	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1205	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1206	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1207	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1208	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1209	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1210	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			Days	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
			1201	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1202	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1203	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1204	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1205	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1206	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1207	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1208	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1209	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
			1210	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

[a] : Number of dead animals/Number of total animals, N : Normal

Table 2. Body weight (Unit : g)

Group	Animal Number	First week induction phase	Second week induction phase	Third week induction phase	Challenge phase
G1	1101	360.37	413.81	475.76	590.51
	1102	344.85	403.62	461.91	580.46
	1103	368.51	453.61	505.74	668.05
	1104	350.58	401.20	459.95	603.77
	1105	335.88	403.28	471.60	645.22
	Mean	352.04	415.10	474.99	617.60
	S.D	12.80	22.08	18.41	37.46
G2	1201	338.07	386.44	450.22	585.71
	1202	353.12	398.41	469.56	609.79
	1203	357.28	411.45	492.57	658.81
	1204	325.05	381.34	439.36	574.82
	1205	336.49	387.16	420.40	562.61
	1206	373.59	428.76	504.41	720.33
	1207	344.51	403.37	473.11	615.89
	1208	347.93	397.57	437.04	618.09
	1209	347.97	399.74	440.83	580.94
	1210	350.42	418.01	476.05	611.98
	Mean	347.44	401.23	460.36	613.90
	S.D	13.08	14.85	26.95	46.46

S.D. : Standard Deviation

Table 3. Evaluation of the skin response

Group	Animal Number	24 h[a]			48 h[a]		
		skin response score	Mean score	Sensitization Rate (%)	skin response score	Mean score	Sensitization Rate (%)
G1	1101	0	0.0	0.0	0	0.0	0.0
	1102	0			0		
	1103	0			0		
	1104	0			0		
	1105	0			0		
G2	1201	0	0.0	0.0	0	0.0	0.0
	1202	0			0		
	1203	0			0		
	1204	0			0		
	1205	0			0		
	1206	0			0		
	1207	0			0		
	1208	0			0		
	1209	0			0		
	1210	0			0		

[a] : observation times

11. Annexes

Annex 1. Information sheet for the test sample (Submitted by sponsor)

Information sheet for the test sample (Medical device)

* Please fill in the fields with information as accurate as possible.
* If you have no information about the test sample, check the N.A.

1. Basic information

Page (1/2)

Date : 23/04/04	Name : Woo chang Kwon (sign)
Test sample	
Test sample name	Kinesiology tape
Item name	Kinesiology tape
Model name	B Balance tape
■Lot No. / □batch No. / □serial No.	230401
Manufacturer	Tntech Inc
Expiration date	□ (years since manufactured) ■ N.A.
Appearance	5cm x 5m roll type Cotton or silk or Hemp B balance tape are suitable for taping any part of the body. They are made of high quality eco-cotton and do not contain latex, which eliminates the occurrence of allergic reactions. The high breathability of the tape allows your skin to breathe freely, so that it does not get stuck under the tape.
Storage condition	■ Room temperature(1 – 30) ℃ □ Refrigerator(2 – 8) ℃ □ Freezer(-25 – -10) ℃ □ Others( )
Classification of the test sample	■ Final product □ Semi-final product □ Specimen
Delivery amount	■ 11 ea □ Others ( )
Treatment after the end of study	□ Return ■ Dispose (※ In KTR, storage of a part sample)

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Annex 1. (Continued)

2. Additional information

Page (2/2)

Preparation of the test sample			
Condition of test sample preparation			■ Direct use ☐ Extraction ☐ Others ( )
Preparation for prior to use			☐ ( ) ■ N.A.
Contact part			■ Attachment Tape
Extraction	Extraction ratio (Test sample / vehicle)		☐ 0.2 g/mL (irregular shaped) ☐ 3 cm^2/mL (≧0.5 mm thick) ☐ 6 cm^2/mL (<0.5 mm thick) ☐ Others ( )
	Extraction condition		☐ 37 ℃, 24 h ☐ 37 ℃, 72 h (reason :) ☐ 50 ℃, 72 h ☐ 70 ℃, 24 h ☐ 121 ℃, 1 h ☐ Others ( )
	Extraction vehicle		☐ Physiological saline ☐ Cottonseed oil ☐ Sterilized distilled water ☐ MEM with 10 % serum (*In vitro* cytotoxicity test) ☐ DMSO (Bacterial reverse mutation assay, *In vitro* mammalian chromosomal aberration test) ☐ PEG 400* (Bacterial reverse mutation assay, *In vitro* mammalian chromosomal aberration test) ☐ Corn oil (*In vivo* mammalian erythrocyte micronucleus test) ☐ PBS (Hemolysis test) ☐ LAL reagent water (Endotoxin mediated pyrogenicity) ☐ Sesame oil (Subacute/subchronic systemic toxicity test) ☐ Others ( ) * Diluted to physiological osmotic pressure
Implantation test	Test sample character		☐ Absorption / degradation (Period :) ☐ N.A.
	Control sample		☐ USP High density polyethylene ☐ Others ( )
Acute systemic toxicity test	Application pathway	Polar vehicle	☐ Intra-venous ☐ Intra-peritoneal ☐ Per oral ☐ Others ( )
		Non-polar vehicle	☐ Intra-peritoneal ☐ Per oral ☐ Others ( )
Subacute/ Subchronic Systemic toxicity test	Control sample		☐ USP High density polyethylene ☐ Others ( )
	Application pathway		☐ Subcutaneous ☐ Intra-muscle ☐ Bone ☐ Intra-venous ☐ Intra-peritoneal ☐ Per oral ☐ Others ( )
	Clinical exposure dose		※ Calculation for systemic toxicity test dose ☐ ( ) ☐ N.A.
Attachment			☐ Information provide by sponsor (Technical document, etc.) ☐ Others ( )
Remark			(Any information that we should know)

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(End)

Annex 2. Receipt of the test sample

Receipt of sample

Receive	Tntech Inc.			
Send	Address	12-63, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, 58141, Korea		
Contact Information	E-mail	sinhwa@ktr.or.kr		
	Telephone	+82-61-370-7937	Fax	+82-61-370-7777

Name of sample	Kinesiology tape
■Lot No. / □batch No. / □serial No.	230401
Receipt amount	MGK-2023-000526 : 11 ea
Receipt date	2023-04-27
Storage condition	Room temperature (1 – 30) ℃
KTR code	MS-01490

KTR confirmed receipt of sample

Received by : Park sin-hwa

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Annex 3. Positive control data

1. Experimental number : TNK-2023-000060

2. Experimental period : 2023-01-26 - 2023-03-03

3. Test sample

Test sample : DNCB (1-chloro-2,4-dinitrobenzene)
Batch No. : BCCD8094
Appearance : Pale yellow crystals

4. Preparation of the test sample

Test sample : In the induction and challenge phase, DNCB was dissolved in cottonseed oil at concentrations of 1.0 and 0.3 % (w/v).
Negative control : Cottonseed oil

5. Evaluation of the skin response

Group	Animal Number	24 h[a]			48 h[a]		
		skin response score	Mean score	Sensitization Rate (%)	skin response score	Mean score	Sensitization Rate (%)
Negative control	1101	0	0.0	0.0	0	0.0	0.0
	1102	0			0		
	1103	0			0		
	1104	0			0		
	1105	0			0		
Positive control	1201	1	1.4	100.0	1	1.3	100.0
	1202	1			1		
	1203	2			2		
	1204	2			2		
	1205	2			2		
	1206	1			1		
	1207	2			1		
	1208	1			1		
	1209	1			1		
	1210	1			1		

[a] : Observation times