Evaluation of a Sample Provided by

[redacted]

Utilizing the Dermal Irritection® Test Method

June 5, 2023

INVITRO INTERNATIONAL

INVITRO INTERNATIONAL
Corporate Office
330 E. Orangethorpe Ave., Ste. D
Placentia, California 92870
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

June 5, 2023

[redacted]

Dear Mr. [redacted]

Enclosed is a copy of the final report detailing the results of our study of the material that was sent to us for analysis by the Irritection® Assay System.

We are delighted that you have selected InVitro International to perform this analysis for you. We look forward to being able to provide additional services for you in the future.

Sincerely,

W. Richard Ulmer
Chairman & CEO

UTILIZATION OF THE IRRITECTION® ASSAY SYSTEM TO EVALUATE A SAMPLE PROVIDED BY

Study Completion Date: June 5, 2023

Client:

Contact:

Phone Number:

Testing Laboratory: InVitro International
330 E. Orangethorpe Ave., Ste. D
Placentia, CA 92870
Phone: (949) 851-8356
Fax: (949) 851-4985

Director of R&D, QA: Amy Wang 6/5/2023
Amy Wang, M.S. Date

President of
InVitro International, Inc. A Jhalani 6/5/2023
Atul Jhalani Date

Approved by:
Chairman & CEO of
InVitro International, Inc. W. Richard Ulmer 6/5/2023
W. Richard Ulmer Date

EXECUTIVE SUMMARY

A single sample was evaluated with the Dermal Irritection test method in order to predict its potential to cause dermal irritation. The results of the study indicated that the sample of was a dermal non-irritant.

TEST REPORT

Test Report #	19W-009119	Date of Report Issue:	June 24, 2019
Date of Sample Received:	June 18, 2019	Pages:	Page 1 of 10

CLIENT INFORMATION:

Company:	Mr Hankeys Toys
Address:	support@mrhankeystoys.com

SAMPLE INFORMATION:

Product Name:	Hankey's Toys Platinum Silicone Formulation
Style No.:	-
Order No.(PO No.):	-
Country of Origin:	United States
Country of Distribution:	Europe, United States
Testing Period:	06/18/2019-06/24/2019

OVERALL RESULT: PASS

Please refer to the following pages for test result summary and appropriate notes.

TEST REPORT

Test Report #	19W-009119	Date of Report Issue:	June 24, 2019
Date of Sample Received:	June 18, 2019	Pages:	Page 2 of 10

TEST RESULTS SUMMARY:

At the request of the client, the following tests were conducted:

CONCLUSION	TEST(S) CONDUCTED
PASS	California Proposition 65, Total Lead in Substrate Materials
PASS	Regulation (EC) No. 1907/2006 REACH Annex XVII, Item 23 Cadmium in Substrate Materials
PASS	California Proposition 65, Total Cadmium in Substrate Materials
PASS	Regulation (EC) No. 1907/2006 REACH Annex XVII, Item 20 Organostannic Compounds
PASS	Regulation (EC) No. 1907/2006 REACH Annex XVII, Item 50 Polycyclic Aromatic Hydrocarbon (PAH)
PASS	California Proposition 65, Phthalates (DBP, BBP, DEHP, DINP, DIDP, DnHP)

DETAILED RESULTS:

California Proposition 65, Total Lead in Substrate Materials

Test Method: CPSC-CH-E1001-08.3 (Metal), CPSC-CH-E1002-08.3 (Non-Metal)
Analytical Method: Inductively Coupled Plasma-Optical Emission Spectrometry

Specimen No.	1+2+3	---	---	---	---	**Limit (mg/kg)**
Test Item	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	
Total Lead (Pb)	ND	---	---	---	---	**100**
Conclusion	PASS	---	---	---	---	

Note:
mg/kg =Milligrams per kilogram
LT = Less than
ND = Not detected (Reporting Limit =15 mg/kg)
Composite results are based on specimen of least mass resulting in highest potential concentration.

Remark:
The specification is quoted from client's requirement.

DETAILED RESULTS:

Regulation (EC) No. 1907/2006 REACH Annex XVII, Item 23 Cadmium in Substrate Materials

Test Method: ASTM F963-17 Clause 8.3.1
Analytical Method: Inductively Coupled Plasma-Optical Emission Spectrometry

Specimen No.	1+2+3	---	---	---	---	**Limit (mg/kg)**
Test Item	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	
Total Cadmium (Cd)	ND	---	---	---	---	**100**
Conclusion	PASS	---	---	---	---	

Note:
mg/kg = Milligrams per kilogram
LT = Less than
ND = Not detected (Reporting Limit = 15mg/kg)
Composite results are based on specimen of least mass resulting in highest potential concentration.

DETAILED RESULTS:

California Proposition 65, Total Cadmium in Substrate Materials

Test Method: ASTM F963-17 Clause 8.3.1
Analytical Method: Inductively Coupled Plasma-Optical Emission Spectrometry

Specimen No.	1+2+3	---	---	---	---	**Limit (mg/kg)**
Test Item	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	
Total Cadmium (Cd)	ND	---	---	---	---	**75**
Conclusion	PASS	---	---	---	---	

Note:
mg/kg =Milligrams per kilogram
LT = Less than
ND = Not detected (Reporting Limit = 15 mg/kg)
Composite results are based on specimen of least mass resulting in highest potential concentration.

Remark:
The specification is quoted from client's requirement.

DETAILED RESULTS:

Regulation (EC) No. 1907/2006 REACH Annex XVII, Item 20 Organostannic Compounds

Test Method: ISO/TS 16179:2012
Analytical Method: Gas Chromatography with Mass Spectrometry

Specimen No.	1+2+3	---	---	---	---	**Limit (mg/kg)**
Test Item	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	
Tributyltin (TBT)	ND	---	---	---	---	**1000**
Triphenyltin (TPT)	ND	---	---	---	---	**1000**
Dibutyltin (DBT)	ND	---	---	---	---	**1000**
Dioctyltin (DOT)	ND	---	---	---	---	**1000**
Conclusion	PASS	---	---	---	---	

Note:
mg/kg = Milligrams per kilogram
LT = Less than
ND = Not detected (Reporting Limit =10mg/kg)
Composite results are based on specimen of least mass resulting in highest potential concentration.

DETAILED RESULTS:

Regulation (EC) No. 1907/2006 REACH Annex XVII, Item 50 Polycyclic Aromatic Hydrocarbon (PAH)

Test Method: AfPS GS 2014:01
Analytical Method: Gas Chromatography with Mass Spectrometry

Toys and childcare articles:

Specimen No.		1+2+3	---	---	---	**Limit (mg/kg)**
Test Item	CAS No.	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	
Benzo [a] pyrene (BaP)	50-32-8	ND	---	---	---	**0.5**
Benzo [e] pyrene (BeP)	192-97-2	ND	---	---	---	**0.5**
Benzo [a] anthracene (BaA)	56-55-3	ND	---	---	---	**0.5**
Chrysene (CHR)	218-01-9	ND	---	---	---	**0.5**
Benzo [b] fluroranthene (BbFA)	205-99-2	ND	---	---	---	**0.5**
Benzo [j] fluroranthene (BjFA)	205-82-3	ND	---	---	---	**0.5**
Benzo [k] fluroranthene (BkFA)	207-08-9	ND	---	---	---	**0.5**
Dibenzo [a,h] anthracene (DBAhA)	53-70-3	ND	---	---	---	**0.5**
Conclusion		PASS	---	---	---	

Note:
mg/kg = Milligrams per kilogram
LT = Less than
ND = Not detected (Reporting Limit = 0.2 mg/kg)
Composite results are based on specimen of least mass resulting in highest potential concentration.

DETAILED RESULTS:

California Proposition 65, Phthalates (DBP, BBP, DEHP, DINP, DIDP, DnHP)

Test Method: CPSC-CH-C1001-09.4
Analytical Method: Gas Chromatography with Mass Spectrometry

Specimen No.		1+2+3	---	---	---	**Limit (mg/kg)**
Test Item	CAS No.	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	Result (mg/kg)	
Dibutyl phthalate (DBP)	84-74-2	ND	---	---	---	**1000**
Benzyl butyl phthalate (BBP)	85-68-7	ND	---	---	---	**1000**
Di-(2-ethylhexyl) phthalate (DEHP)	117-81-7	ND	---	---	---	**1000**
Diisononyl phthalate (DINP)	28553-12-0 68515-48-0	ND	---	---	---	**1000**
Diisodecyl phthalate (DIDP)	26761-40-0 68515-49-1	ND	---	---	---	**1000**
Di-n-hexyl phthalate (DnHP)	84-75-3	ND	---	---	---	**1000**
Conclusion		PASS	---	---	---	

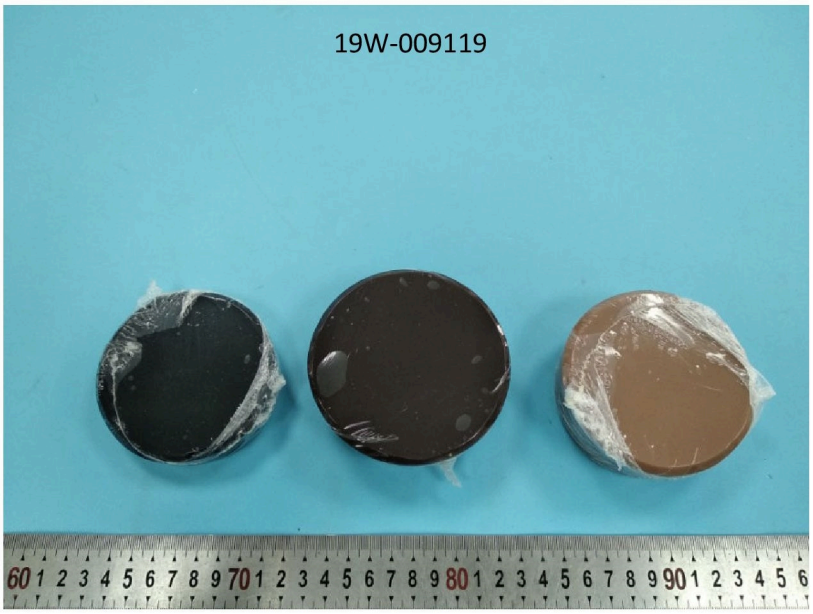
Note:
mg/kg (Milligrams per kilogram) = 0.0001 % m/m (Percent by mass)
LT = Less than
ND = Not detected (Reporting Limit = 150 mg/kg)
Composite results are based on specimen of least mass resulting in highest potential concentration.

Remark:
The specification is quoted from client's requirement.

SPECIMEN DESCRIPTION:

Specimen No.	Specimen Description	Location
1	Light flesh soft silicone 75%	Cylinder block
2	Black soft silicone 75%	Cylinder block
3	Dark Brown soft silicone 75%	Cylinder block

SAMPLE PHOTO:



-End Report-

TEST FACILITY

MB Research Laboratories
1765 Wentz Rd.
P.O. Box 178
Spinnerstown, PA 18968
(215) 536-4110

CLIENT

Test Report No: MB 16-24539.19	Date: August 25, 2016

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by MB Research Laboratories.

DATE OF RECEIPT: Samples were received at MB Research Laboratories facilities on June 3, 2016.

PROTOCOL: 713-02

TEST REQUESTED: Evaluate for the potential to elicit delayed dermal contact sensitization. This study was conducted based on the requirements of OECD TG 439, in accordance with the EU classification R38 and GHS category 2 requirements: Tests for irritation and skin sensitization.

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Matthew Troese, Ph. D., Study Director

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V20-5897-2	Date: December 1, 2020

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: November 11, 2020 – November 13, 2020

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President, Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V20-5897-3	Date: December 1, 2020

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: November 11, 2020 – November 13, 2020

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President, Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V21-5962.04	Date: October 18, 2021

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 13, 2021 – October 15, 2021

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-4711.02	Date: October 13, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 5, 2022 – October 7, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-3775.02	Date: August 9, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: August 3, 2022 - August 5, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-4711.07	Date: October 13, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 5, 2022 – October 7, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-4711.03	Date: October 13, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 5, 2022 – October 7, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-4711.05	Date: October 13, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 5, 2022 – October 7, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-4711.04	Date: October 13, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 5, 2022 – October 7, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For:

TEST FACILITY

MB Research Laboratories
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(215) 536-4110

CLIENT

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DATE OF RECEIPT: Samples were received at MB Research Laboratories facilities on June 3, 2016.

PROTOCOL: 713-02

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PERFORMED BY: Matthew Troese, Ph. D., Study Director

Prepared For:

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TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Matthew Troese, Ph. D., Study Director

Prepared For:

TEST FACILITY

Consumer Product Testing Company
70 New Dutch Lane
Fairfield, NJ 07004-2514
(973) 808-7111

CLIENT

Test Report No: V22-4711.06	Date: October 13, 2022

SAMPLE ID: The client identified the following test material as

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by Consumer Product Testing Company.

TEST INTERVAL: October 5, 2022 – October 7, 2022

PROTOCOL: The MatTek Corporation *In Vitro* EpiDerm™ Skin Irritation Test (EPI-200-SIT)

TEST REQUESTED: To predict skin irritation potential of neat test substances in the context of identification and classification of skin irritation hazard according to the EU classification system. The Modified EpiDerm SIT allows discrimination between irritants of category 2 and non-irritants. The protocol used is in compliance with OECD 439 (Adopted 18 June 2019).

TEST RESULTS: The test article showed no evidence of causing dermal contact sensitization and was classified as a non-irritant.

PERFORMED BY: Steven Nitka, B.S., Vice President/Laboratory Director (Study Director)

Prepared For: