



rtbeauty.com.hk)Art Beauty Group Company Limited (www.artb

Date	: 2021-06-25 rt Beauty Group Company Limited (www.a	Page 2 of 21
pany Limited (www.arto	: HC21040678	

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Test Report

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Reputy Group Company Limited (www.arto

1 (www. N	Date Io.	: 20 : H	021-06-25 t Beauty Group Company Lint C21040678	Page 4 of 21
1	•	Intro	oduction	
(www	/.artk	oeauty 1.1	Purpose	
			The purpose of this study was to evalu irritation in rabbit. .com.hk) Art Beauty Group Company Limi	uate the test article for the potential to cause skin ted (www.artbeauty.com.hk) Art Beauty Group Company Limited
		1.2	Testing Guidelines This study was based on the requirem 10993-10:2010, Biological evaluation sensitization.	ents of the International Organization for Standardization of medical devices - Part 10: Tests for irritation and skin
		1.3 beauty	Dates (Comble) Art Beauty Group Company Limi Test Article Received:	2021.04.25
			Test Started: Observations Concluded:	2021.05.22 2021.05.28 com.hk) Art Beauty Group Company Limited
			The Hong Kong Stan	dards and Testing Centre Limited

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2. Identification of Test and Control Articles

ompany Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artb

The test article provided by the sponsor was identified and handled as described below:

Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb Table 1 Test Article

1	able 1 - Test Afficie	oup Company Line	
pany Limited (www.artbe	Name	Surgical Face Mask	
	Size	175mm×95mm	
	CAS:	N.A. (construct beauty.com.hk.) Art Beauty Group Compar	
	Model hk) Art Beauty Gro	N.A.	
pany Limited (www.artoe	Lot	N.A.	
	Initial State	Not Sterilized	
	Strength, Purity and	1 st Laver: PP: 2 nd Laver: Mel Blown: 3 rd Laver: PP	
arthe	Composition Beauty Gro	1 Dayor. 11, 2 Layor. Wer blown, 5 Layor. 11	
bany Limited (www.arto	Color	Blue	
	Physical Description	Solid Group Compan	
	of the Test Article	Company Limited (www.artbeauty.com.hk) Art Beauty Croup	
	Manufacture Date	N.A.	
bany Limited (What	Expiration Date	N.A.	

Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited(www Table 2 - Negative Control Article

	auty com.hk) Art Beauty Gro Name	Sodium chloride injection (SC) Soybean oil (SO)	and the set of the
	Purity, Composition, and Other any comments Art Beauty Gro Characteristics:	SC: Composition: 0.9% NaCl ± 5.0% of label claim, balance is water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 SO: Composition: CAS No.: 8001-22-7	y Limited (www.aru
Т	able 3 - Reagents	oun Company Limited (www.artbeauty.com.hk) Art Beauty Group Compan	y Limited (www.artu

Table 3 - Reagents

and (www.artbe	Namen.hk) Art Beauty Gri	Brand	Lot	
pany Limited (www.s	SC	Jiangxikelun	C20092904	a constant
	SO	Tianyushan	20201201 Beauty Group Compan	y Limited (www.arts

uty.com.hk) Art Beauty Group Company Limited (www.artb

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om hk.) Art Beau10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong

Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

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k)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artb pany Limited (W3. Test System -Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artb 3.1 Test System pany Limited (www.artbeauty. Species: Rabbit (Oryctolagus cuniculus) New Zealand White Strain: Guangzhou Huadu Xinhua Animal Farm y Group Company Limited (www.artb Source: Art Beauty Group Compan Male & Female (Females were nulliparous and Sex: nonpregnant) Young adult Age:

Acclimation Period:	Minimum 5 daystbeauty.com.hk) Art Beauty Group Company a
Number of Animals:	6
Identification Method:	Name card
e turona lok) Art Beauty Group Co	

pany Limited (www.artl 3.2^{,ty} Test System management

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO testing standards. The rabbit is widely used for this Limited (www.artb purpose and relative ranking of irritant scores can be determined.

The Hong Kong Standards and Testing Centre Limited m hk.) Art Beau10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group This report shall not be reproduced unless with prior written approval from The Hong Kong Standards and Testing Centre Limited. For Conditions of Issuance of this test report, please refer to the overleaf and Website.



$\mathbf{D}_{\mathrm{any}}$ Limited (www.	ate : 2021-06-25 t Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (Page 7 of 21 5. : HC21040678	
any Limited(www.	artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited	
<u>+.</u>	Annual Wanagement	
	4.1 Husbandry, Housing and Environment	
	Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed. Art Beauty Group Company Limited	
	The animal housing room is conventional system lab. The lab animal using license : SYXK(Guangdong Province)2019-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 19-26°C and the relative humidity was set to 40-70%. There were no significant	
	antbeauty commonly temperature or relative humidity excursions that adversely affected the health of the animals.	
	The light cycle was controlled (12 hours light, 12 hours dark).	
	4.2 Food, Water and Contaminants artbeauty Food: Laboratory animal formula feed (rabbit), Shenyang maohua biotechnology co. LTD, was provided daily.	
	Water: The water quality met the "Sanitary standard for drinking water"	
	artbeauty. (Cellen in 2000)	
	Food and water were sterile. No contaminants present in the feed and water impacted any Limited the results of this study. artbeauty.com.hk.) Art Beauty Group Company Limited (www.artbeauty.com.hk.) Art Beauty Group Company Limited (artbeauty.com.hk.)	
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pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb

4.3 Personnel

Associates involved in this study were appropriately qualified and trained. Group Company Limited (www.artb pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com

4.4 Veterinary Care

pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb

4.5 IACUC

This procedure has been approved by the STC Institutional Animal Care and Useany Limited (www.artb Committee (IACUC), and is reviewed at least annually by the same committee.

om.hk)Art Beauty Group Company Limited (www.artb 4.6 Selection Only healthy, animals free from irritation or other dermatological lesions that could pany Limited (www.artbeauty.commer) Art Beauty Closer selected.

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Method 5.

5.1 Test and Control Article Preparation (www.artbeauty.com.hk) Art Beauty Group Co

pany Limited (www.artbeauty. The preparations of the test article and the negative control were subjected to the extraction conditions as described below. The extracts were continuously agitated pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb

Vehicle	Treatment Group	Extraction Ratio	Article Amount	Volume of	Extraction Condition
Nort Beauty C	broup CTestany Lir	$3 \text{ cm}^2/\text{mL}$	332.5 cm^2	110.8 mL	
50	Control	N. A	N. A	20 mL	50±2°C for
50	Test	$3 \text{ cm}^2/\text{mL}$	332.5 cm^2	110.8 mL	72±2 h
50	Control	N. A	auty (N:A ik) Al	t B 20 mL	Company Linnes

pany Limited(www.artbeauty.com.hk)Art Beauty Group Comp

The Hong Kong Standards and Testing Centre Limited om hk.) Art Beau10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group This report shall not be reproduced unless with prior written approval from The Hong Kong Standards and Testing Centre Limited. For Conditions of Issuance of this test report, please refer to the overleaf and Website.



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The following table contains a description of the test and control article extracts before Nrt Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty and after extraction.

	-

Table 5 - Condi	tion of Extract	5				1
** • • •	Time	Extract	Con	(www.art		
venicle	Beauty Group L		Color	Clarity	Particulates	
	Before	Test	Colorless	Clear	None	
	Extraction	Control	Colorless	rt BeClear roup	Com None	(www.art
.com.hk) Art Beauty	Group Company After	Test	Colorless	Clear	None	
SC	Extraction	Control	Colorless	Clear	None	(www.art
	Duinates Hoov	Test	Colorless A	rt BeClear	None	(
.com.hk) Art Beauty	Prior to Use	Control	Colorless	Clear	None	
	Before	Test	Colorless	Oily	None	(www.artl
	Extraction	Control war	Colorless	Oily	None	
(.com.hk) Art Beauty	After	Test	Colorless	Oily	None	
SO	Extraction	Control	Colorless	Oily	ComNoneimited	(www.artl
	Group Company	Limite Test www.ar	Colorless	Oily	None	
/.COTLINK / AR DOT .	Prior to Use	Control	Colorless	Oily	None	

The test article extracted in SC and SO remained unchanged during the extraction process.^d The extracts were maintained at ambient temperature <24 hours before use for all phases. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

uty.com.hk) Art Beauty Group Company Limited (www.artb

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Statute (www.artbeauty Group Company Limited (www.artb **Test Report**

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Group Company Limited(www.artbeauty.com.hk)Art Beauty Group Company Limited(www.artb

bany Limited (www.ar 5.2.1/ Laboratory Observations

- 1. Animals were observed daily for general health.
- 2. Body weights were recorded for each animal at pretreatment.
- 3. Dermal observations for erythema and edema were recorded at 1, 24, 48 and

pany Limited (www.artbeauty.com 72 hours after patch removal in accordance with the criteria in Appendix 1.

Table 6 Classification System for Skin Reaction w.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb

pany Limited (www.artbe	Erythema and Eschar Formation	Numerical Grading	Edema Formation	Numerical Grading	
	No erythema	0	No edema Art Beauty	Group $oldsymbol{\hat{0}}$ ompar	y Limited (www.arto
in the communication	Very slight erythema	ompany Limited	Very slight edema (barely	1	
pany Limited (www.anse	(barely perceptible)	1	perceptible)	1	
			Well-defined edema (edges of	Group Compar	y Limited (www.artb
	Well-defined erythema	ompan <mark>2</mark> Limited	area well-defined by definite	2	
pany Limited (www.artbe	auty.com.hk) Art Beauty Cloup		raising)		
	Moderate eruthema	3	Moderate edema (raised	2	v Limited (www.arth
	Widder ale ei ythema	J	approximately 1 mm) ^{Beauty}	Group Sompar	y Linitoo (
in a communication	Severe erythema (beet	ompany Linnes	Savara adama (raisad mara than		
pany Limited (www.ares	redness) to eschar	4	1 mm and autonding houand	Л	
	formation preventing	4		4 Group Compar	y Limited (www.arto
	grading of erythema	ompany Limited	(www.artexposure area)		
pany Limited (www.artbe	auty.com.nk) Are boards Total p	ossible score f	or irritation	8	

pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb

ity.com.hk) Art Beauty Group Company Limited (www.artb

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Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb

bany Limited (www.arto Table 7 Irritation Response Categories in the Rabbit Irritation Response Categories in the Rabbit Mean Score Response Category eauty.com.hk) Art B Negligible 0-0.4 0.5 - 1.9Slight 2.0-4.9 eauty Group Compar Moderate auty.com.hk) Art Bea Severe 5-8 All times and temperatures reported here in are approximate and are within ranges pany Limited (www.artb established by the external standards described in the References section of this report pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group **Evaluation** 6. The Primary Irritation Index of the test was calculated following test completion for each animal. The erythema and edema scores obtained at the 24, 48 and 72-hour intervals were added together and divided by the total number of observations. This calculation was conducted separately for the test and control article for each animal. The score for the control was any Limited (www.artb subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score for each animal was added together and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was characterized based on the pany Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artb The Hong Kong Standards and Testing Centre Limited hk) Art Beau10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong Website: www.stc.group Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group This report shall not be reproduced unless with prior written approval from The Hong Kong Standards and Testing Centre Limited. For Conditions of Issuance of this test report, please refer to the overleaf and Website.



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Group Company Limited(www.artbeauty.com.hk)Art Beauty Group Company Limited(www.artb

Results 7.

All the animals were clinically normal throughout the study. Individual results of dermal scoring are presented in Appendix 1. No irritation was observed on the skin of the animals. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown below:uty.com.hk) Art Beauty Grou

Table 8 Irritation Calculations of SC Group

Animal Number	B Test Score Score Average	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category	
20210218 (the auty $01^{m.hK}$) Ar	Beat <mark>0</mark> y Gro	up Company 0	Limited (www 0	V.al (Denar)			
20210429 01	0	0	0	0	0	Negligible	
20210429 rtbeauty 03m.hk) Ar	: Beal ⁰ y Gro	up Co 0 npany	Limited (www	v.artbeauty.com.hk	An Doudy		

Table 9 Irritation Calculations of SO Group

ntbeauty.com.hk) Ar Animal Number	Beauty Gro Test Score Average	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category	(www
04 20210429	0	0	0				
20210429 05	0	0	0 Limited (www	v.artbeauQy.com.hk) Art Be q uty Gro	up Company Limited Negligible	(www
20210429) Ar 06	Beauty Gro 0	0	0				
) Art Beauty Gro	up Company Limited	(www

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8. Conclusion	
There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Indexes for the test article extracts were both calculated to be 0.0, any Limited (The response of the test article extracts was categorized as negligible.	
Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.	
STC archive files in accordance with STC SOPs.	
10. ISO Compliance	
10. ISO Compliance All procedures were compliance to ISO 17025.	
10. ISO Compliance All procedures were compliance to ISO 17025. And Beauty Contribution (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Ar	
10. ISO Compliance All procedures were compliance to ISO 17025. www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art	
10. ISO Compliance All procedures were compliance to ISO 17025. All procedures were compliance to ISO 17025. www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www	
10. ISO Compliance All procedures were compliance to ISO 17025. ^{11Ed} (www.artbeauty.com.trk.) Art Beauty Group Company Limited (www.artbeauty.com.trk.) Art Beauty Group Company Lim	

heauty.com.hk) Art Beauto Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group This report shall not be reproduced unless with prior written approval from The Hong Kong Standards and Testing Centre Limited. For Conditions of Issuance of this test report, please refer to the overleaf and Website.

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11. References	
(www.artbeauty.commun.com	
Laboratory Studies	
International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).	
Linear bk) Art Beauty Group Company Limited	
International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2006).	
International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization (2010).	
International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2012). Beauty Group Company Limited	
(www.International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).	
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y Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artb **Appendix 1 – Dermal Observations**

pany Limited (www.artbeauty.com.hk

	Table 10	Dermai Ob	servations	of SC Group										
	Animal	Waiaht	Current	u otompani (Limi	ted (www.art	Interval	(hours)	Group Compa	ny Limited					
	Limited (v number (g)		Group	Observation	1	24	48	72						
			Test	Erythema	0	0 beauty.com.h	() Art Beauty	Group 0 Compa	ny Limited					
	2021021	021021 th / .com.hk) A 801	t Beauty Gro	Edema	0	0	0	0						
	801		Control	Erythema	0	0	0	0 Group Compa	ny Limited					
	www.artbeaut/.com.	y.com.hk) A	t Beauty Gro	Edema	ted (www.arl 0	0	0	0						
	Ellinoa (021042 901 2826.6		Test	Erythema	0	0	0	0	ny Limited				
	2021042		t Beauty Gro	up CEdema Limi	ted (10 ww.arl	beauty.com.h	() Art Beauty 0	0						
	901		~2020.0	-2020.0	2820.0	2820.0	C a set se 1	Erythema	0	0	0	0	United	
			Control	Edema Limi	ted (www.arl	beaut .0 com.hi	() Art $\mathbf{\hat{0}}^{eauty}$	Group Compa 0	ny Limited					
	(www.artbeauty	021042	3144.5 com.hk.) At Beauty Gro 3144.5	Erythema	0	0	0	0						
20	2021042			Edema	0 ted (www.arl	0 beauty.com.hl	() Art 0 eauty	Group 0 Compa	ny Limited					
	903 ww.artbeaut	y.com.hk) A		Erythema	0	0	0	0						
-			Control	Edema	0	0	0 Art Beauty	Group 0 compa	ny Limited					

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nd_(www.artbeauty.com.hk) Art Beauty Group Company Limited(www.artb Table 11 Dermal Observations of SO Group

			sci vations	of SO Oroup					
pany Limited (w	Animal	y.com.hk) A	t Beauty Gro	up Company					
	number	Weight (g)	Group	Observation	1	24	48 Ant seauty	Grou 72 ompa	
pany Limited (W	ww.artbeaut	y.com.hk) A	t Beauty Gro	Erythema	0	0	0	0	
	2021042	2007.2	Test	Edema	0	0	0	0 Group Compa	
	904	2987.3 _{v.com.hk}) A	t Beauty Gro	up Erythema	ted ($\overset{www.arl}{0}$	beauty.com.n 0	0	0	
bany Limited (W	WW.altocade	anout		Edema	0	0	0	0	
	ww.artbeaut	w.artbeaut/.com.hk) A 2021042 905	^{t Be} Test Gro	Erythema	ted (0 ww.arl	beaut <mark>:0</mark> com.h	<) Art Beauty 0	Group Compa 0	
pany Limited (w				Edema	0	0	0	0	
	905			Erythema	0 ted (www.arl	beauty0com.h	<) Art 0 eauty	Group <mark>C</mark> ompa	
pany Limited (w	ww.artbeaut	y.com.hk) A	Control	Edema	0	0	0	0	
			Test t Beauty Gro	Erythema	0	0 heauty.com.h	() Art Beauty	Group 0 Compa	
any Limited (W	v2021042	021042 ^{tt} /.com.hk.) A		up Company Lim Edema	0	0	0	0	
July	906	3117.5		Erythema	0	0	0	0 Group Compa	
	www.artbeaut	y.com.hk) A	t Beauty Gro	up Edema Limi	ted (www.arl 0	beauty.com.n 0	0	0	
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The Hong Kong Standards and Testing Centre Limited

com.hk) Art Beau 10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong

Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

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Date : 2021-06-25 rt Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb : HC21040678 No. Appendix 2 – Periodic Positive Control Study for Primary Skin Irritation Test ty Group Company Limited (www.arth What was tested sodium dodecyl sulfate (SDS) Dates Treatment Started: 2021.02.21 Observations Concluded: 2021.02.24 Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb **Purpose**: pany Limited (ww A periodic positive control study was conducted for the Primary Skin Irritation Test to meet the following objectives: 1) confirm the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, 2) substantiate the potential of SDS to cause irritant effects, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the rabbit strain to primary skin irritation test. () Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb Methods : The test utilized young adult, 2 female rabbits (nulliparous and not pregnant) & 1 male rabbit supplied by Guangzhou baiyun district longgui xingke animal farm. The weight at study initiation ranged from 2kg to 4kg. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml 20% (w/w) concentration of SDS was topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 om.<u>h</u>k) Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artb and 72 hours after removal of the single application. **Results**: All the three sites demonstrated a positive skin irritation to the known skin irritant, SDS. None of the control sites of animals demonstrated an irritation response. The Irritation Calculations pany Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk The Hong Kong Standards and Testing Centre Limited m hk.) Art Beau 10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong

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pany Limited (ww	w.artbeauty.com.hk) Animal Number w.artbeauty.com.hk)	Art Beauty C Test Score Average Art Beauty C	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score ty c (CPIS)	Primary Irritation Index (CPIS/3)	Response Category _{par}	y Limited(www.artb
bany Limited (2020111203	8	0	8				
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The known skin irritant SDS produced evidence of causing primary skin irritation in the New pany Limited (www.Zealand White strain of rabbit. Therefore, the following objectives were met: 1) the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization was confirmed, 2) the potential for SDS to cause skin any Limited (www.artb irritation was substantiated, 3) proper training of the technicians performing this study design pany Limited (wwwas verified and 4) the susceptibility of the New Zealand White rabbit strain to skin irritation was substantiated.

pany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artb The Hong Kong Standards and Testing Centre Limited om hk.) Art Beau10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong Tel: +852 2666 1888 Fax: +852 2664 4353 Website: www.stc.group Email: hkstc@stc.group

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