

Klinion Latex Exam Gloves Powder Free	Document number: 1207	
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### Allergy Test report

USM Malaysia:	Lot. No:	Purpose:	Reference:	Result:
Week 1	P 9050494	Sensitisation Study in the Guinea pig	EN 10993-10	ER/0 – ED/0
Week 2	P 9050494	Sensitisation Study in the Guinea pig	EN 10993-10	ER/0 – ED/0
Week 3	P 9050494	Sensitisation Study in the Guinea pig	EN 10993-10	ER/0 – ED/0

### Allergy Test report

USM Malaysia:	Lot. No:	Purpose:	Reference:	Result:
24 Hours	P 9050494	Skin Irritation study in the Rabbit	EN 10993-10	ER/0 – ED/0
48 Hours	P 9050494	Skin Irritation study in the Rabbit	EN 10993-10	ER/0 – ED/0
72 Hours	P 9050494	Skin Irritation study in the Rabbit	EN 10993-10	ER/0 – ED/0

Sensitivity & Irritant Score of (ER) Erythematic:		Sensitivity & Irritant Score of (OE) Oedema:	
None.....0		None.....0	
Very Slight.....1		Very Slight.....1	
Well Defined.....2		Well Defined.....2	
Moderate.....3		Moderate.....3	
Severe.....4		Severe.....4	

### Allergy Test report

Fit Biotech Finland:	Reference:	Result (µg/g):				
E2TD	EN455-3:2006	Hev b 1	Hev b 3	Hev b 5	Hev b 6.02	TOTAL
		0.05	0.11	0.20	0.15	0.51 µg/g

### Chemical Residual Test report

MRB Malaysia:	Chemicals:	Reference:	Method:	Result:
Test 1	Tetramethylthiuram disulphide (TMTD) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 2	Mercaptobenzothiazole (MBT) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 3	Zinc Diethyldithiocarbamate (ZDEC) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 4	Zinc Dimethyldithiocarbamate (ZDMC) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 5	Zinc Pentaylmethyldithiocarbamate (ZPMC) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 6	Zinc Dibuthyldithiocarbamate (ZDBC) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 7	Zinc Mercaptobenzimidazolates (ZMBI) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 8	Zinc Mercaptobenzothiazole (ZMBT) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 9	Butylhydroxytoluene (BHT) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 10	Butylhydroxyanisole (BHA) (µg/g)	UPB/P/003a	HPLC <sup>1</sup>	Non Detected
Test 11	Diphenyl guanidine (DPG) (µg/g)	UPB/P/003a	HPLC	Non Detected
Test 12	Diphenyl Thiourea (DPT) (µg/g)	UPB/P/003a	HPLC	Non Detected

### Cytotoxicity Effect report

SIRIM Malaysia:	Chemical:	Reference:	Method:	Result:
Lot: 1612229	ATCC CCL 81, Vero cells	ISO 10993-5	MEM Elution Assay	Grade 4 at 13% Dilution of Extract

### Food Safe Test report

SGS Taiwan:	Method:	Reflux with:	7 hours reflux	Additional 2 hrs reflux	Result
			Total extractive, mg/in <sup>2</sup>	Total extractive, mg/in <sup>2</sup>	
Lot: 16120909	21 CFR 177.2600	Distilled water	0.8	0.4	Pass
		Requirement Max	20	1	
Lot: 16120909	21 CFR 177.2600	n-Hexane	9.3	1.8	Pass
		Requirement Max	175	4	

### Microbiological Test report

SGS Malaysia:	Lot. No:	Method:	Reference:	Result:
Total Aerobic Count	2511515	BS 5763-1	EN 455-3	< 10 cfu/g
E. Coli (presumptive)	2511515	BS 5763-8	EN 455-3	< 3 MPN/g
Yeasts & Moulds	2511515	BS 5763-12	EN 455-3	< 10 cfu/g
Salmonella/25g	2511515	BS 5763-4	EN 455-3	Absent
Staphylococcus aureus	2511515	BS 5763-7	EN 455-3	< 10 cfu/g
Pseudomonas aeruginosa	2511515		EN 455-3	< 10 cfu/g

### Protein Test report

MRB:	Lot. No:	Reference:	Result:
Sample 1	08045109 / M	EN 455-3	14 µg/g

### Viral Penetration Test report

NELSON USA:	Lot. No:	Challenge <sup>2</sup>	Challenge <sup>3</sup>	Assay <sup>4</sup>	Method:	Result:
Sample 1	PY 2712239	1.9 x 10 <sup>8</sup>	2.1 x 10 <sup>8</sup>	<1 <sup>a</sup>	ASTM F1671-97b	Pass
Sample 2	PY 2712239	1.9 x 10 <sup>8</sup>	2.1 x 10 <sup>8</sup>	<1 <sup>a</sup>	ASTM F1671-97b	Pass
Sample 3	PY 2712239	1.9 x 10 <sup>8</sup>	2.1 x 10 <sup>8</sup>	<1 <sup>a</sup>	ASTM F1671-97b	Pass
Description		Concentration Before (PFU <sup>5</sup> /mill)	Concentration After (PFU/mill)	Titter (PFU/mill)		Yes

USM - University Sains Malaysia

MRB - Malaysian Rubber Board

<sup>1</sup> HPLC is a apparatus to measure the presence of one or more specific chemicals

<sup>2</sup> The concentration of the ΦX174 bacteriophage before test was performed

<sup>3</sup> The concentration of the ΦX174 bacteriophage after test was performed

<sup>4</sup> Concentration of ΦX174 bacteriophage of the collected assay

<sup>5</sup> Plaque forming unit