





#### Safe, non-irritating, wide-spectrum, alternative preservative system

In response to the skincare market's pursuit of zero burden on skin and clean beauty in recent years, ImDerma Lab has tested hundreds of permutations and combinations and selected (1) available ingredients that meet the cosmetics regulations of various countries, but are not listed on the front of preservatives. The mild ingredients in the list and the EWG index is 1; (2) High safety: Pass the OECD439 skin irritation test (no skin irritation) & OECD 442C sensitization test (no skin sensitization); (3) Effective preservative system-passed the EU ISO 11930 Criteria A test in a variety of formulation tests.

Microbiological management is an important issue in cosmetics: it needs to be effective and safe

- Quality Control
- Prevent microbial secondary pollution
- Safe to skin
- Ban of some traditional ingredients:
  - Parabens
  - IPBC
  - MI/MCI
  - Ocean Friendly





# **Powerful, Safe to skin!**

• All ingredients are rated at 1 by EWG





- Non-irritative confirmed by OECD 439 Skin Irritation Test.
- Non-sensitive confirmed by OECD 442C method.





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# Standards for the control of microorganisms in cosmetics in various countries

Country/Gro up	The number of bacteria in the product (CFU/g 或 mL)		Specific bacteria that must not be
	For infants, around the eyes, and for contact with mucous membranes	All others	detected
WHO	≤100	≤1000	E. coli, P. aeruginosa, S. aureus
EU (COLIPA)	≤100	≤1000	P. aeruginosa, S. aureus, C. albicans
Taiwan	≤100	≤1000	E. coli, P. aeruginosa, S. aureus, C. albicans
Japan	≤100	≤1000	E. coli, P. aeruginosa, S. aureus Salmonella
USA (CTFA)	≤100	≤1000	E. coli, P. aeruginosa, S. aureus
China**	≤500	≤1000	Fecal Coliforms, P. aeruginosa, S. aureus



#### **MIC (Minimum Inhibition Concentration)**

# Only 1% has a good antibacterial effect!

• The minimum inhibitory concentration (MIC) was tested by the ImDerma P2 level microbiology laboratory, and the results showed that a concentration of 1% has a good antibacterial effect.



NC : Culture medium + bacteria、PC : Antibiotic + Bacteria、 Blank : Culture medium

Species	MIC (%)
Escherichia coli	0.7
Pseudomonas aeruginosa	0.7
Staphylococcus aureus	0.7
Candida albicans	0.7
Aspergillus brasiliensis	0.7



#### **ISO 11930 Challenge Test**

### Imdermalab<sup>®</sup> Guard 100 pass the challenge test!

 Imdermalab® Guard 100 with a concentration of 1% was added to the samples of liquid and lotion respectively for testing. The results showed that from the day of inoculation to the 7th day, no growth of the five bacteria was detected. No bacteria was detected from the 14th to the 28th, and it passed the ISO 11930 criteria A.



Log reduction values ( $R_x = IgN_0 - IgN_x$ )			
	requi T <sub>7</sub>	red T14	T28
Bacteria	≥3	≥3 and NI	≥3 and NI
C. a	≥1	≥1 and NI	≥1 and NI
A. b	-	≥0	≥1

ISO 11930 criteria A

- In this test, an acceptable range of deviation of 0,5 log is accepted. (see 5.7)
- NI: no increase in the count from the previous contact time.
- $R_x=0$  when  $IgN_0=IgN_x$  (no increase from the initial count).

#### **Challenge Test – Repeated dosing of bacteria**

#### Imdermalab<sup>®</sup> Guard 100 pass the repeated dosing of bacteria test

• Fresh bacteria are implanted every week in the face mask samples in large packages on the market (which will be repeatedly opened), and samples are taken every week to observe the growth of bacteria to test the antiseptic efficacy. The experimental results showed that the samples were replanted with 1.5% concentration every week, and no bacteria were detected on the 7, 14, 21, 28, and 35 days. It passed ISO 11930 criteria A.



#### Safety Accessment

# Imdermalab<sup>®</sup> Guard 100 is safe to skin!

It is tested with 3D skin and judged as No Category according to OECD TG 439, which means it • has no skin irritation and the data meets OECD requirements.



ACCEPTANCE CRITERIA (OECD 439)	
$1.2 \le OD_{570}$ of NC, SD $\le 18 \%$ PC < 40 % of NC, SD $\le 18 \%$ SD of TS $\le 18 \%$	
<i>In vitro</i> result	In vivo prediction
mean tissue viability $\leq 50$ %	Category 2: Irritant
mean tissue viability > 50 %	No Category



PC

Imdermalab<sup>®</sup> Guard 100

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#### **Stability**

### Imdermalab<sup>®</sup> Guard 100 With light and heat resistance

• Place Imdermalab® Guard 100 under light, room temperature and high temperature for 4 weeks, and observe the color change in 1, 2, 4 weeks. The experimental results show that the above conditions will not cause any color change.



#### **pH Compatibility**

### Imdermalab<sup>®</sup> Guard 100 is compatible in wide pH range

• Formulated Imdermalab® Guard 100 at pH 3~8 for 4 weeks, and observe the color change at 1, 2, 4 weeks. Experimental results show that Imdermalab® Guard 100 is not affected by pH and has broad-spectrum antibacterial properties that are rare in the market.



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#### **Ion Tolerance**

# Imdermalab<sup>®</sup> Guard 100 with ion tolerance

Place Imdermalab® Guard 100 with 1, 3, and 5% NaCl for 4 weeks, and observe the color change at 1, 2, and 4 weeks. Experimental results show that Imdermalab® Guard 100 is not affected by ion changes and has ion tolerance.





#### **Compatible with polymer**

### Imdermalab<sup>®</sup> Guard 100 is compatible with most polymer in formulas

- Add 1-2% of Imdermalab Guard 100 in different polymer and observed for 4 weeks, no color change of formula is observed.
- Imdermalab® Guard 100 was mixed with Xanthan Gum, HEC, HPMC, Carbomer and AVC and other different polymers to detect the change in viscosity. The experimental results showed that the viscosity of the formula was not affected by Imdermalab® Guard 100.

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#### Comparison

#### Imdermalab<sup>®</sup> Guard 100 v.s other alternative preservative product

	Sym***e®	Guard 100
EWG	1	1
Appearance	Liquid	Clear Liquid
Convenience of operation	When using, it is necessary to dissolve the powder product in alcohol solution, confirm the appropriate ratio and retest the antiseptic effect (such as: phenoxyethanol, hexylene glycol, potassium sorbate, etc.)	Just add directly to the water phase, easy to disperse in the formula
Dosage	1-2% (must with polyol)	1%
MIC	E.coli 0.4%、P.a 0.4%、 S.a 0.6%、C.a 0.6%、A.b 0.4%	E.coli 0.06%、P.a 0.03%、 S.a 0.06%、C.a 0.02%、A.b 0.01%
Skin-irritation	Low-None	None
Eye-irritation	medium irritation	none-mild irritation
Others	Because the phenolic structure itself is easy to oxidize	Has the ability to inhibit MMP and moisturize Heavy metal ions may produce color due to chelation

ES.



- Ingredients are not listed as preservative in the EU, Japan, and Taiwan.
- EWG is 1 and passed the safety assessment, no skin irritation, no sensitization
- MIC test is 1% effective; passed the 28-day challenge test and passed the repeated dosing of bacteria test
- Broad-spectrum antibacterial (pH 3~8)
- It has the characteristics of light resistance, heat resistance, ion resistance, and no obvious compatibility contraindications
- Applicable dosage forms: liquid, emulsion, lotion products
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## Imdermalab<sup>®</sup> Guard 100

INCI NAME	Propanediol (and) 1, 2-Hexanediol (and) Caprylhydroxamic Acid (and) Dipropylene Glycol (and) Diglycerin
Form	Liquid
Appearance	Transparent
pH	4.5~6.5, at 25°C
Suggested Dosage	0.8%~2%
Storage Condition	Sealed and stored in temperature & moisture control environment





# Imdermalab<sup>®</sup> Guard 100-C

INCI NAME	Propanediol (and) 1, 2-Hexanediol (and) Caprylhydroxamic Acid (and) Caprylyl glycol (and) Dipropylene Glycol (and) Diglycerin (and) Dipotassium Glycyrrhizinate
Form	Liquid
Appearance	Transparent
pH	4.5~6.5, at 25°C
Suggested Dosage	1%~2%
Storage Condition	Sealed and stored in temperature & moisture control environment



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# Imdermalab<sup>®</sup> Guard 100+ ("plus")

INCI NAME	Propanediol (and) 1, 2-Hexanediol (and) Caprylhydroxamic Acid (and) Dipropylene Glycol (and) Ethylhexylglycerin (and) caprylyl glycol
Form	Liquid
Appearance	Transparent
pH	4.5~6.5, at 25°C
Suggested Dosage	0.8%~2%
Storage Condition	Sealed and stored in temperature & moisture control environment



Innovative · Efficient · Safe

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