NULASTIN GENTLE EXFOLIATING CLEANSER
Preservative Efficacy Test (PET)

Certified Laboratories
A Certified Group Company
Specializing in Cosmetics, OTC, Dietary Supplements and Toys/Gadgets

Report Date: 9/20/2023
Date Received: 8/8/2023
Date Completed: 9/12/2023
P.O. #:3544
Accession #: 41403

SAMPLE DESCRIPTION:
Sample Name: Gentle Exfoliating Cleanser
Product Code: 15102-02
Batch/Lot #: 126-071823A

TEST PERFORMED:	MQL METHOD #	METHOD REFERENCE#
PCPC	TM-03	M-3 Method for Preservation Efficacy Testing of Water Miscible Personal Care Products

Procedure Summary:

1. 10 different organisms are inoculated at levels of 1 x 10^5 to 1 x 10^6 colony forming units (CFU) per gram for bacteria and 1 x 10^4 to 1 x 10^5 (CFU) per gram for yeast & mold.
2. The inoculated test samples are stored at 20-25°C for 28 days.
3. The population of each challenge microorganism is determined by plate count method at Day 2, 7, 14, 21, and 28.
4. The plate counts are performed at a 1:10 initial dilution using Modified Letheen Broth as the diluent and Tryptic Soy and Sabouraud Dextrose agar, as determined by the plate count validation for this product.

Initial results:

Initial Aerobic Plate Count CFU/g	*Initial Yeast –Mold Count* CFU/g
<10	<10

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M-3 Method for Preservation Efficacy Testing of Water Miscible Personal Care Products

PRESERVATION EFFICACY TESTING:

	Preservation Efficacy Testing Colony Forming Units / gram					
Organism	Inoculum / g	Day 2	Day 7	Day 14	Day 21	Day 28
Staphylococcus aureus ATCC 6538	***7.46x 10^5***	$3.00x10^4$	$1.70x10^4$	$9.00x10^3$	<10	<10
Escherichia coli ATCC 8739	***8.84x 10^5***	<10	<10	<10	<10	<10
Pseudomonas aeruginosa ATCC 9027	***8.54x 10^5***	<10	<10	<10	<10	<10
Candida albicans ATCC 10231	***5.97x 10^4***	<10	<10	<10	<10	<10
Aspergillus brasiliensis ATCC 16404	***5.01x 10^4***	<10	<10	<10	<10	<10
Pseudomonas fluorescens ATCC 13525	***1.26x 10^6***	<10	<10	<10	<10	<10
Pseudomonas putida ATCC 49128	***1.28x 10^6***	TNTC~10^5	<10	<10	<10	<10
Enterobacter cloacae ATCC 13047	***1.10x 10^6***	<10	<10	<10	<10	<10
Klebsiella pneumoniae ATCC 13883	***1.38x 10^6***	TNTC~10^5	$4.40x10^4$	$1.20x10^3$	<10	<10
Burkholderia cepacia ATCC 25416	***7.36x 10^5***	<10	<10	<10	<10	<10

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LOG REDUCTION CALCULATION FROM INITIAL INOCULUM

	7 DAYS	14 DAYS	28 DAYS
Staphylococcus aureus ATCC 6538	1.64	1.92	4.87
Escherichia coli ATCC 8739	4.95	4.95	4.95
Pseudomonas aeruginosa ATCC 9027	4.93	4.93	4.93
Candida albicans ATCC 10231	3.78	3.78	3.78
Aspergillus brasiliensis ATCC 16404	3.70	3.70	3.70
Pseudomonas fluorescens ATCC 13525	5.10	5.10	5.10
Pseudomonas putida ATCC 49128	5.11	5.11	5.11
Enterobacter cloacae ATCC 13047	5.04	5.04	5.04
Klebsiella pneumoniae ATCC 13883	1.50	3.06	5.14
Burkholderia cepacia ATCC 25416	4.87	4.87	4.87

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Microbial Content Test Agar (Bacteria)
Sabouraud Dextrose Agar (Yeast and Mold)

NEUTRALIZER SUITABILITY:

	Neutralizer Suitability Validation				
Organism	Inoculum	Dilution	Microbial Recovery	Diluent	Percent Recovery
Staphylococcus aureus ATCC 6538	**68cfu/plate**	**1:10**	**60cfu/plate**	**LB**	**88.24 %**
Escherichia coli ATCC 8739	**53cfu/plate**	**1:10**	**51cfu/plate**	**LB**	**96.23 %**
Pseudomonas aeruginosa ATCC 9027	**52cfu/plate**	**1:10**	**48cfu/plate**	**LB**	**92.31 %**
Candida albicans ATCC 10231	**51cfu/plate**	**1:10**	**36cfu/plate**	**LB**	**70.59 %**
Aspergillus brasiliensis ATCC 16404	**73cfu/plate**	**1:10**	**73cfu/plate**	**LB**	**100.00 %**
Pseudomonas fluorescens ATCC 13525	**60cfu/plate**	**1:10**	**59cfu/plate**	**LB**	**98.33%**
Pseudomonas putida ATCC 49128	**54cfu/plate**	**1:10**	**54cfu/plate**	**LB**	**100.00%**
Enterobacter cloacae ATCC 13047	**95cfu/plate**	**1:10**	**73cfu/plate**	**LB**	**76.84%**
Klebsiella pneumoniae ATCC 13883	**76cfu/plate**	**1:10**	**70cfu/plate**	**LB**	**92.11%**
Burkholderia cepacia ATCC 25416	**78cfu/plate**	**1:10**	**56cfu/plate**	**LB**	**71.79%**

CFU = Colony Forming Units LB = Letheen Broth
Diluent: Letheen Broth Dilution: 1:10

NEUTRALIZER SUITABILITY RESULTS:

Based on the data observed, recovery of the test organisms confirms the suitability of the test method PCPC M3.

SEP 2 0 2023

Reviewed by: Connie Truong Date:
Microbiologist

SEP 2 0 2023

Approved by:Monica Ayala Date:
Microbiologist

EUROPEAN PHARMACOPEIA ACCEPTANCE CRITERIA

TABLE 5.1.3.-2: Ear Preparations, nasal preparations, preperations for cutaneous application and preparations for inhalation

Log 10 Reduction		2d	7d	14d	28d
Bacteria	A	2	3	-	NI
	B	-	-	3	NI
Yeast/Mold	A	-	-	2	NI
	B	-	-	1	NI

NI = No Increase NR = No Recovery log1 = 90% log 2 = 95% log 3 = 99.9%

The A criteria express the recommended efficacy to be achieved. In justified cases where the A criteria cannot be attained, for example for reasons of an increased risk of adverse reactions, the B criteria must be satisfied. (EP-9th edition).

UNITED STATES PHARMACOPEIA ACCEPTANCE CRITERIA

CATEGORY 2: Topically used products made with aqueous bases or vehicles; nonsterile nasal products and emulsions, including those applied to mucous membranes

Log 10 Reduction	14d	28d
Bacteria	NLT 2.0 log reduction from initial count	NI from 14 day count
Yeast/Mold	NI from initial count	NI from initial count

NI = No Increase NR = No Recovery log1=90% log2=95% log3=99.9%

The requirements for antimicrobial effectiveness are met if the criteria specified in Table 3 are met [...]."No increase" in counts is defined as NMT 0.5 $\log_{10}$ unit more than the value to which it is compared. (USP-43)

JAPANESE PHARMACOPEIA ACCEPTANCE CRITERIA

CATEGORY 1B: Topically used non-sterile products

Log 10 Reduction	14d	28d
Bacteria	NLT 2.0 log reduction from initial count	NI from 14 day count
Yeast/Mold	NI from initial count	NI from initial count

NI = No Increase NR = No Recovery log1 = 90% log 2 = 95% log 3 = 99.9%

When the results described in Table 3 are obtained, the product examined is considered to meet the requirement of the test. (JP XVII)

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PCPC M-3 Determination Of Preservation Efficacy In Water-Miscible Products

	Log 10 Reduction			
Organism Type	7d	14d	21d	28d
Bacteria	≥3	NI	NI	NI
Yeast/Mold	≥1	NI	NI	NI

PCPC M-4 Preservation Efficacy Testing Of Eye-Area Personal Care Products

	Log 10 Reduction			
Organism Type	7d	14d	21d	28d
Bacteria	>3	Continued reduction	Continued reduction	>4 (to less than detectable)
Yeast/Mold	>1	Continued reduction	Continued reduction	Continued reduction
Spore Forming Bacteria	No Increase	No Increase	No Increase	No Increase

PCPC M-5 Preservation Efficacy In Nonwoven Substrate Personal Care Products

	Log 10 Reduction			
Organism Type	7d	14d	21d	28d
Bacteria	≥3	NI	NI	NI
Yeast/Mold	≥1	NI	NI	NI

PCPC M-6 Method For Preservation Testing Of Atypical Products

	Log 10 Reduction				
Organism Type	2d	7d	14d	21d	28d
Bacteria	-	>3	Continued reduction	Continued reduction	>4 (to less than detectable)
Yeast/Mold	-	>1	Continued reduction	Continued reduction	Continued reduction
Spore Forming Bacteria	-	No Increase	No Increase	No Increase	No Increase

PCPC M6: The recommended preservative challenge test methods used for determining the preservative efficacy of aqueous-based products [...] may not be suitable for evaluating certain atypical product formulations. It is the responsibility of the manufacturer to set the challenge test criteria for the product type and form. In the performance of challenge testing of atypical products, the pass/fail criteria may need to be modified in comparison to the preservative challenge test criterion that is commonly used for aqueous based products. (PCPC 2018)

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*A2LA and ISO 17025 accredited.

PRESERVATION EFFICACY TESTING RESULTS:

Based on the results, the preservative is passing PCPC criteria. The preservative is effective in maintaining the sterility of the product.

Reviewed by: Connie Truong Microbiologist	Date: SEP 2 0 2023	Approved by:Monica Ayala Microbiologist	Date: SEP 2 0 2023

*References

1) U.S. Pharmacopeia & National Formulary. 2019. USP 42- NF 37. <51> Antimicrobial Effectiveness Testing, USP-NF, Rockville, MD,pp. 6382.

2) ASTM International 2013. ASTM E1054-08 Standard Practices for Evaluating Inactivators of Antimicrobial Agents. ASTM International, West Conshohocken, PA.

3) PCPC 2018. M-3 Efficacy Testing Of Water Miscible Personal Care Products, Personal Care Products Council. Personal Care Products Council, Washington, D.C.

4) PCPC 2018. M-4 Preservation Efficacy Testing Of Eye Area Personal Care Products, Personal Care Products Council. Personal Care Products Council, Washington, D.C.

5) PCPC 2018. M-5 Preservation Testing Of Nonwoven Substrate Products, Personal Care Products Council. Personal Care Products Council, Washington, D.C.

6) PCPC 2018. M-6 A Method For Preservation Testing Of Atypical Products, Personal Care Products Council. Personal Care Products Council, Washington, D.C.

*Micro Quality Laboratories, Inc. (MQL), is an A2LA ISO 17025 accredited testing laboratory (Certificate Number 3034.01). The requirements of ISO 17025 were followed for the test, results and preparation of this certificate of analysis. MQL's scope of accreditation may be found on A2LA or MQL websites.