

The influence of the test product on the key organisms of the respective body region was examined.

Information about the tested product:

Manufacturer:

Debut Biotechnology, Inc.
11545 Sorrento Valley Dr, St 310
CA 92121 San Diego
USA

Name of the product:

Purifying Whipped Cleanser

Product type:	Final product
Application:	Rinse-off
Dilution:	33% in PBS
Sample received:	15 March 2023
Test Start:	15 March 2023
Test End:	31 March 2023
Test Standard:	MyMicrobiome Standard 18.10 Face
Test result:	2.0
Certification:	Granted

Test description

The MyMicrobiome Standard evaluates cosmetic and personal care products, that encounter the skin or mucous membrane, in terms of their influence on the microbiome located at a specific body site.

An intact skin microbiome has a fundamental influence on skin health. Products which are to be skin-friendly must also be Microbiome-friendly in order not to unbalance the skin of the user.

The MyMicrobiome Standard evaluates the influence of cosmetic and personal care products on the microbial key players of a specific skin or mucous membrane area. The human microbiome is very individual from person to person.

Each area, however, harbors a characteristic composition of bacteria, viruses and fungi. The test examines the products influence on the key organisms typical for each skin area and thus offers a standardized procedure.

Various aspects are examined:

The microbial quality of the product.

The influence of the product on the natural, healthy skin balance.

The skin-commensal bacterium *Staphylococcus epidermidis* keeps the skin with antimicrobial peptides (so-called bacteriocins) and pH adjustments healthy and keeps skin-harmful germs such as *Staphylococcus aureus* in check. The product should not disturb this balance between skin-friendly and skin-harmful bacteria. This sensitive balance is investigated in conjunction with the product.

The influence of the product on the bacterial diversity of the specific body region.

Each body region is colonized by a certain microbial composition. For a healthy skin it is particularly important to maintain this biodiversity. The influence of the product on the respective microbial mixture is examined in the test. The aim is to find as many key organisms as possible after contact with the product.

The influence of the product on the growth behavior of the microbes of the specific body region.

In addition to the diversity of the specific microbiome, the growth or number of different key organisms should not be influenced by the product. This is investigated in a skin-product contact model. The key organisms are brought into direct and indirect contact with the product and their growth is observed.

Results

The microbial quality of the product.

The prerequisite for the test for microbial friendliness is the microbiological quality of the product. The following table contains the limit values that must be observed.

Types of organisms	Limit values	
	Products specially designed for children under 3 years, eye area or mucous skins	Other products
Total counts mesophilic, aerobic microorganisms (bacteria, yeasts, molds, (TAMC and TYMC))	$\leq 1 \times 10^2$ cfu/g or ml ^a	$\leq 1 \times 10^3$ cfu/g or ml ^b
<i>Escherichia coli</i>	Not detectable in 1g or 1 ml	Not detectable in 1g or 1 ml
<i>Pseudomonas aeruginosa</i>	Not detectable in 1g or 1 ml	Not detectable in 1g or 1 ml
<i>Staphylococcus aureus</i>	Not detectable in 1g or 1 ml	Not detectable in 1g or 1 ml
<i>Candida albicans</i>	Not detectable in 1g or 1 ml	Not detectable in 1g or 1 ml
a >200 cfu/g or ml, b >2000 cfu/g or ml		

Results Microbiological quality

Determination of TAMC, TYMC, absence of *E. coli*, *P. aeruginosa* and *S. aureus*.

The microbiological quality of the product according to DIN EN ISO 17516 is fulfilled.

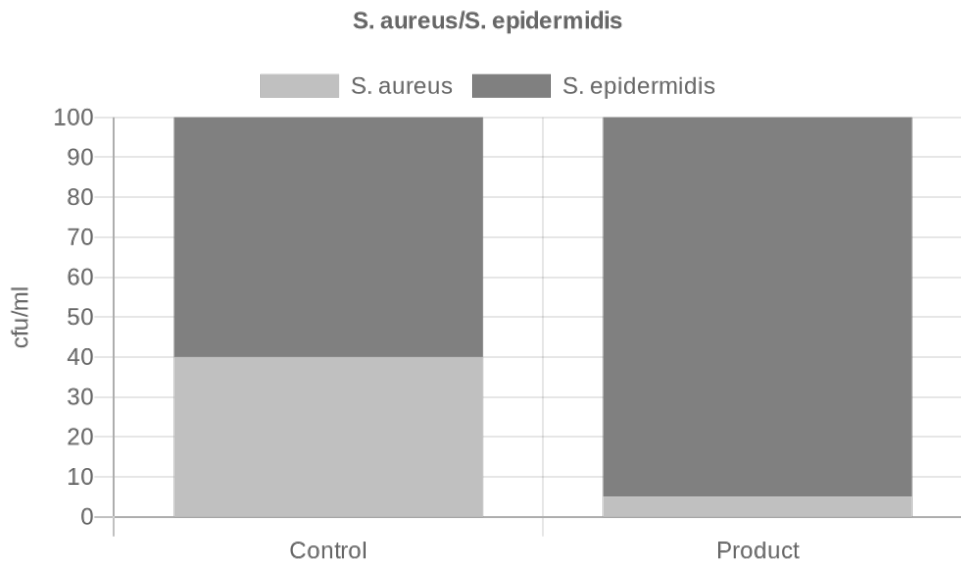
Parameter	Sample no.: 23.607.18.1
TAMC [cfu/0,1 ml]	< 1,0E+01
TYMC (incl. <i>Candida albicans</i>) [in 0,1 ml]	negative
<i>Escherichia coli</i> [in 0,1 ml]	negative
<i>Pseudomonas aeruginosa</i> [in 0,1 ml]	negative
<i>Staphylococcus aureus</i> [in 0,1 ml]	negative

Results

The influence of the product on the natural, healthy skin balance.

A co-culture of *S. epidermidis* and *S. aureus* is incubated with the product.
The ratio of the two microbes to each other is determined.

Determination of the bacterial count at time t = 15 min (rinse-off) or 4h (leave-on).

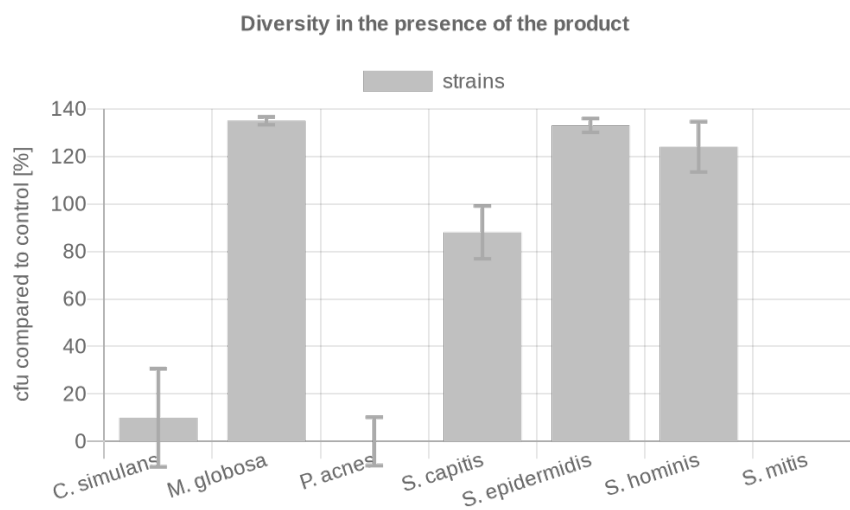


	cfu/ml		Ratio Product/ Control	Grade
	<i>S. aureus</i>	<i>S. epidermidis</i>		
Control	1923.3	2923.3	11.6	1
Product	183.3	3230		

Results – SEBACEOUS -

The influence of the product on the microbial diversity of the specific body region.

A co-culture of key organisms of the specific body region is incubated with the product for t = 15 min (rinse-off) or 4h (leave-on). The ratio of the microbes compared to the control (PBS) is determined.

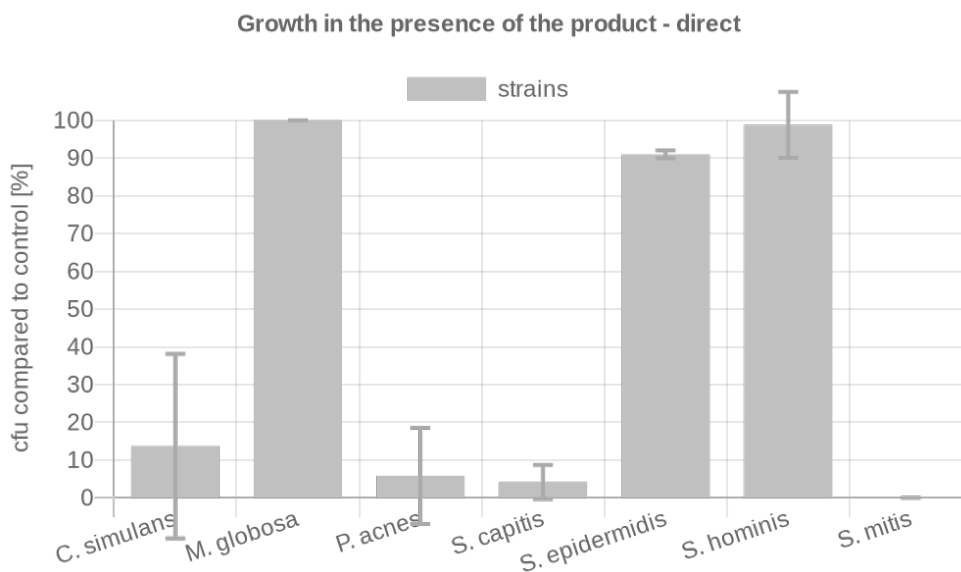


Key-Microbe	t=	15min	Rating
	cfu/ml		
<i>C. simulans</i>	Control	460	3
	Product	46.7	
<i>M. globosa</i>	Control	49300	2
	Product	66500	
<i>P. acnes</i>	Control	313.3	3
	Product	0	
<i>S. capitis</i>	Control	226.7	2
	Product	200	
<i>S. epidermidis</i>	Control	245	2
	Product	326.7	
<i>S. hominis</i>	Control	196.7	1
	Product	243.3	
<i>S. mitis</i>	Control		
	Product		
Overall rating:			2.2

Results – SEBACEOUS -

The influence of the product on the growth behavior of the microbes of the specific body region – directly.

The influence of the product on the growth of each individual microbe of the key organisms of the specific body region is investigated and put in relation to the control (PBS). Product contact with the microorganisms is directly.

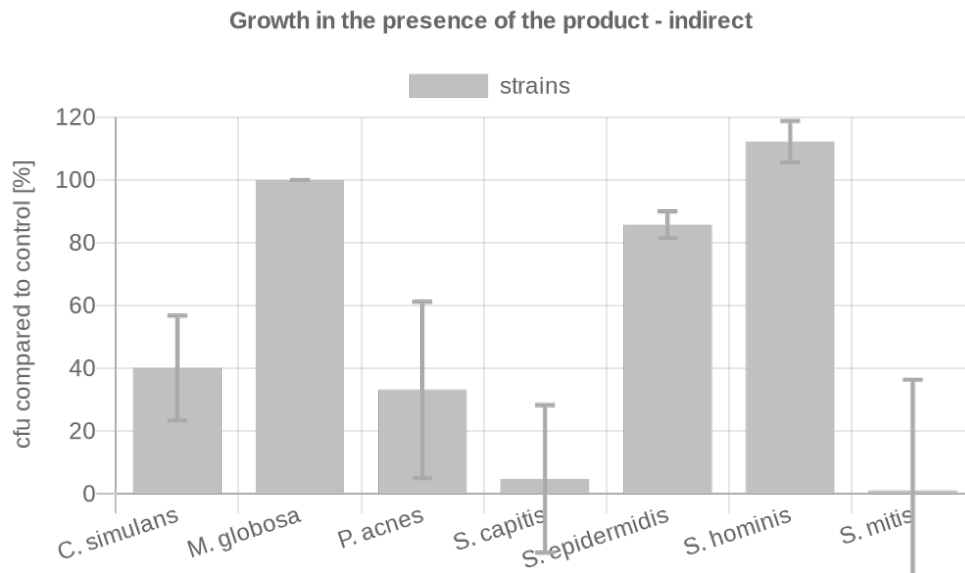


Key-Microbe	cfu/ml		Rating
	Control	Product	
<i>C. simulans</i>	Control	289.3	3
	Product	39.7	
<i>M. globosa</i>	Control	100	1
	Product	100	
<i>P. acnes</i>	Control	417.7	3
	Product	24.3	
<i>S. capitis</i>	Control	732.3	3
	Product	31	
<i>S. epidermidis</i>	Control	829.3	2
	Product	754.5	
<i>S. hominis</i>	Control	363.5	1
	Product	359.3	
<i>S. mitis</i>	Control	147.7	3
	Product	0	
Overall rating:			2.3

Results – SEBACEOUS -

The influence of the product on the growth behavior of the microbes of the specific body region – indirectly.

The influence of the product on the growth of each individual microbe of the key organisms of the specific body region is investigated and put in relation to the control (PBS). The product contact to the microorganisms is indirect.



Key-Microbe	cfu/ml		Rating
C. simulans	Control	282.3	3
	Product	113.3	
M. globosa	Control	100	1
	Product	100	
P. acnes	Control	403.3	3
	Product	133.5	
S. capitis	Control	766.7	3
	Product	37	
S. epidermidis	Control	852.7	2
	Product	731	
S. hominis	Control	364.3	1
	Product	408.7	
S. mitis	Control	155.3	3
	Product	1.7	
Overall rating:			2.3

Results

The results are evaluated with grades from 1 (one) to 3 (three). If the product shows no or positive influence to the above-mentioned aspects, a grade of 1 is awarded respectively.

If only a very weak negative influence can be detected in the tests, the grade 2 is awarded and in case of a clearly negative influence, the product receives the grade 3.

The product has passed up to grade 2.0.

Here the grade means

1.0 – 2.0 = Microbiome-friendly; 2.1 – 3.0 = Microbiome-damaging.

Test	Grade
Balance of the skin microbiome	1
Diversity of the corresponding skin microbiome (x2)	2.2
Skin-product contact direct (x2)	2.3
Skin-product contact indirect	2.3
Overall grade	2.0

With an overall grade of 2.0 the seal „Microbiome-friendly“ is awarded according to MyMicrobiome Standard 18.10 Face.

Place, Date: Balzers, 04 July 2023

Responsible person: Dr. Kristin Neumann

Signature:

