

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

Information about the tested product:

Manufacturer:

Delavie Sciences LLC
365 Plantation St Ste 175
01605 Worcester MA
USA

Name of the product:

Bacillus lysate

Product type:	Final Product
Application:	Leave-on
Dilution:	Non-diluted
Sample received:	21 March 2023
Test Start:	20 March 2023
Test End:	25 April 2023
Test Standard:	MyMicrobiome Standard 18.10 Face
Test result:	2
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.

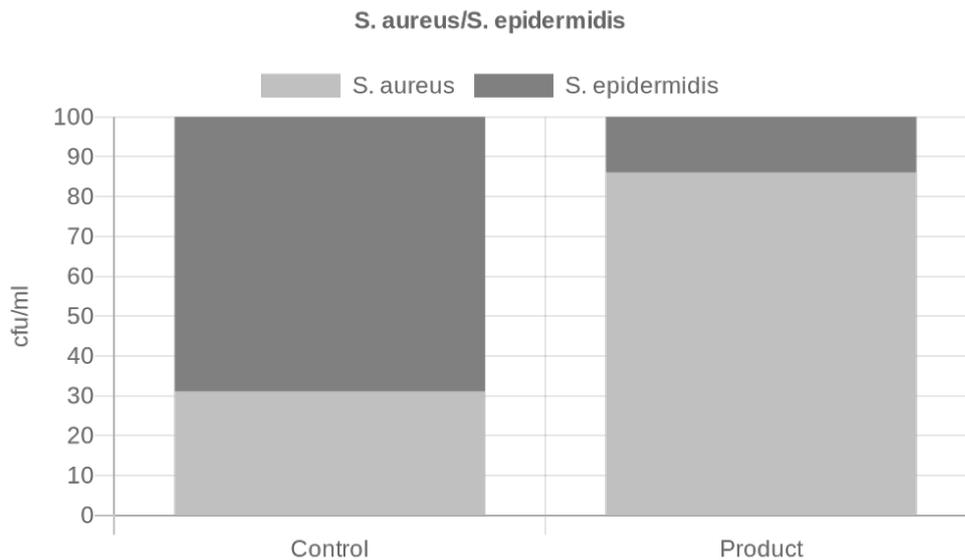
Parameter	Sample no.: 23.621.18.2
TAMC [cfu/0,1 ml]	< 1,0E+01
TYMC (incl. <i>Candida albicans</i>) [in 0,1 ml]	negative
<i>Escherichia coli</i> [in 0,1 ml]	negative
<i>Pseudomonas aeruginosa</i> [in 0,1 ml]	negative
<i>Staphylococcus aureus</i> [in 0,1 ml]	negative

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).

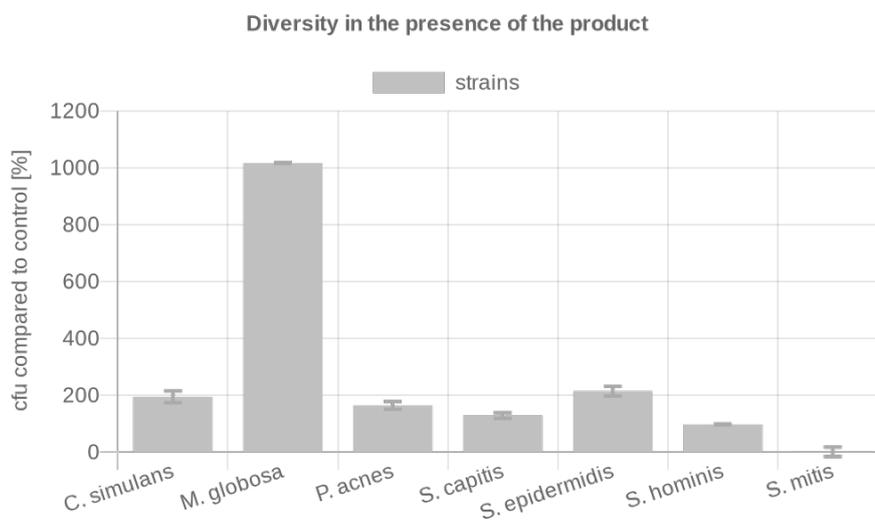


	cfu/ml		Ratio Product/ Control	Grade
	<i>S. aureus</i>	<i>S. epidermidis</i>		
Control	1783.3	3883.3	0.1	3
Product	162433.3	27233.3		

Results

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.

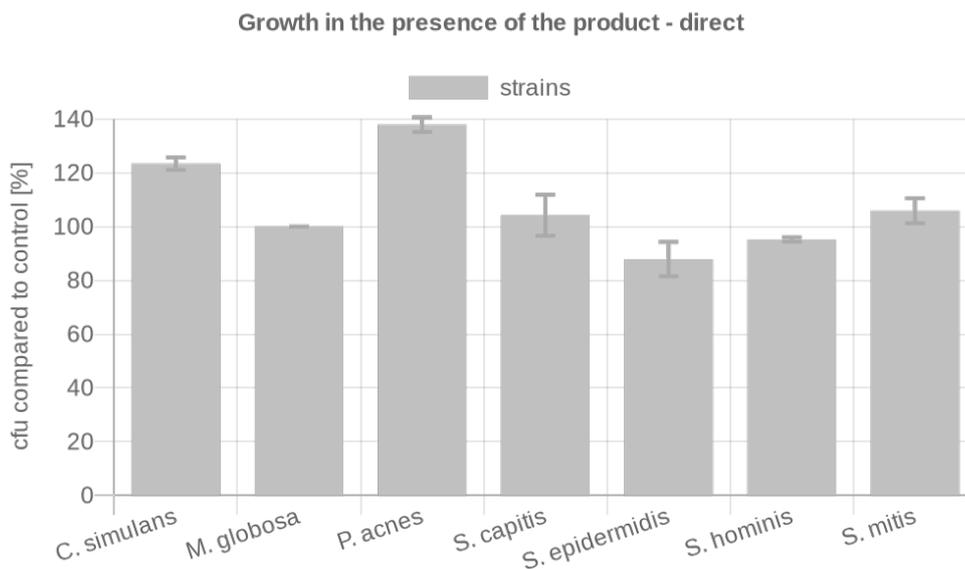


Key-Microbe	t=	4h	Rating
	cfu/ml		
<i>C. simulans</i>	Control	4300	3
	Product	8400	
<i>M. globosa</i>	Control	57466.7	3
	Product	584366.7	
<i>P. acnes</i>	Control	1263.3	2
	Product	2080	
<i>S. capitis</i>	Control	5066.7	2
	Product	6533.3	
<i>S. epidermidis</i>	Control	270	3
	Product	580	
<i>S. hominis</i>	Control	4950	1
	Product	4866.7	
<i>S. mitis</i>	Control	286.7	3
	Product	6.7	
Overall rating:			2.4

Results

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.

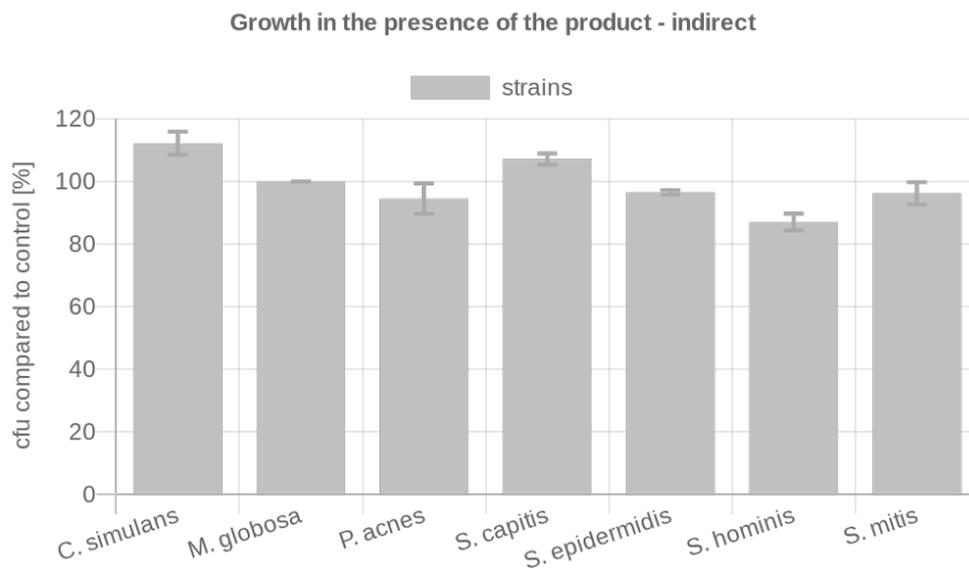


Key-Microbe	cfu/ml		Rating
<i>C. simulans</i>	Control	173	1
	Product	213.5	
<i>M. globosa</i>	Control	100	1
	Product	100	
<i>P. acnes</i>	Control	234.3	2
	Product	323	
<i>S. capitis</i>	Control	258.7	1
	Product	269.5	
<i>S. epidermidis</i>	Control	580.5	2
	Product	510	
<i>S. hominis</i>	Control	647.3	1
	Product	616.5	
<i>S. mitis</i>	Control	461	1
	Product	488	
Overall rating:			1.3

Results

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
<i>C. simulans</i>	Control	205	1
	Product	230	
<i>M. globosa</i>	Control	100	1
	Product	100	
<i>P. acnes</i>	Control	248.7	2
	Product	235	
<i>S. capitis</i>	Control	265	1
	Product	283.7	
<i>S. epidermidis</i>	Control	503.3	1
	Product	485.5	
<i>S. hominis</i>	Control	681.3	2
	Product	593	
<i>S. mitis</i>	Control	457.3	1
	Product	440	
Overall rating:			1.3

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	3
Diversity of the corresponding skin microbiome (x2)	2.4
Skin-product contact direct (x2)	1.3
Skin-product contact indirect	1.3
Overall grade	2

With an overall grade of 2 the seal „Microbiome-friendly“ is awarded according to MyMicrobiome Standard 18.10 Face.

Place, Date: Balzers, 27 April 2023

Responsible person: Dr. Kristin Neumann

Signature:

