

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

Information about the tested product:

Manufacturer:

DR. KADE Pharmazeutische Fabrik GmbH
Rigistraße 2
12277 Berlin
Germany

Name of the product:

KadeFungin® 3 Vaginalcreme

Product type:	Final product
Application:	Leave-on
Dilution:	No
Sample received:	21 September 2023
Test Start:	21 September 2023
Test End:	27 November 2023
Test Standard:	MyMicrobiome Standard 21.10 Vaginal
Test result:	1.7
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.

Here, co-cultures are created with the two most common vaginal microbes, *Lactobacillus crispatus* and the pathogenic bacteria *Gardnerella vaginalis* and are brought into contact with the vaginal product to be tested. After a certain period of time, the ratio of the two microbes is compared to an untreated control group. The product must not affect the natural balance of the microbiome dominated by lactobacilli.

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.

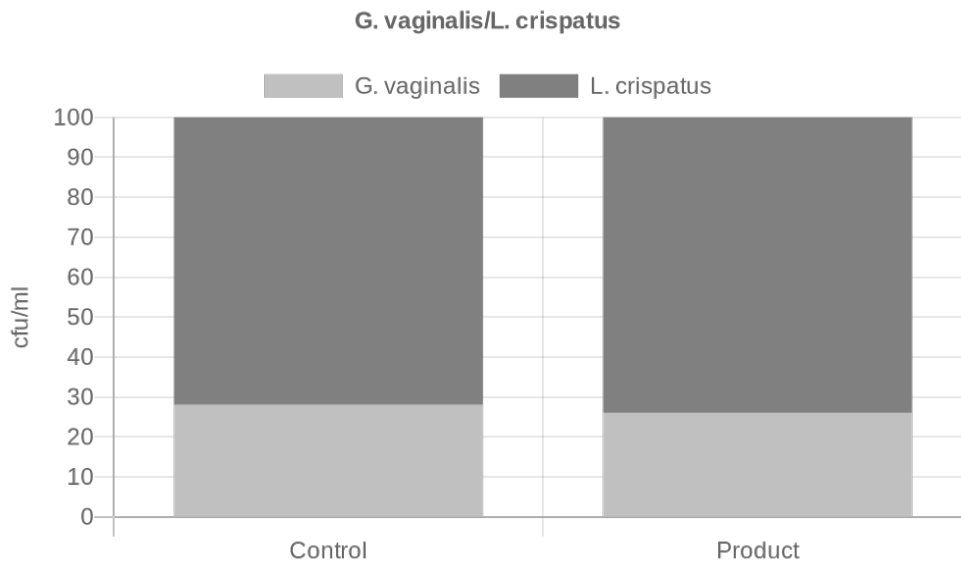
Parameter	Sample no.: 23.732.21.2
TAMC [cfu/0,1 ml]	< 1,0E+01
TYMC (incl. <i>Candida albicans</i>) [in 0,1 ml]	negative
<i>Escherichia coli</i> [in 0,1 ml]	negative
<i>Pseudomonas aeruginosa</i> [in 0,1 ml]	negative
<i>Staphylococcus aureus</i> [in 0,1 ml]	negative

Results

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

A co-culture of *G. vaginalis* and *L. crispatus* 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).

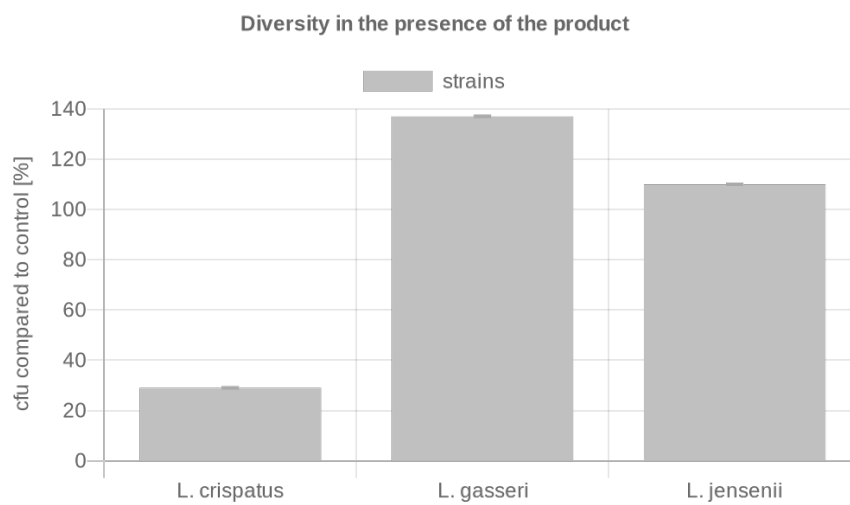


	cfu/ml		Ratio Product/ Control	Grade
	<i>G. vaginalis</i>	<i>L. crispatus</i>		
Control	2133.3	5566.7	1.1	1
Product	3566.7	10033.3		

Results – VAGINAL -

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.

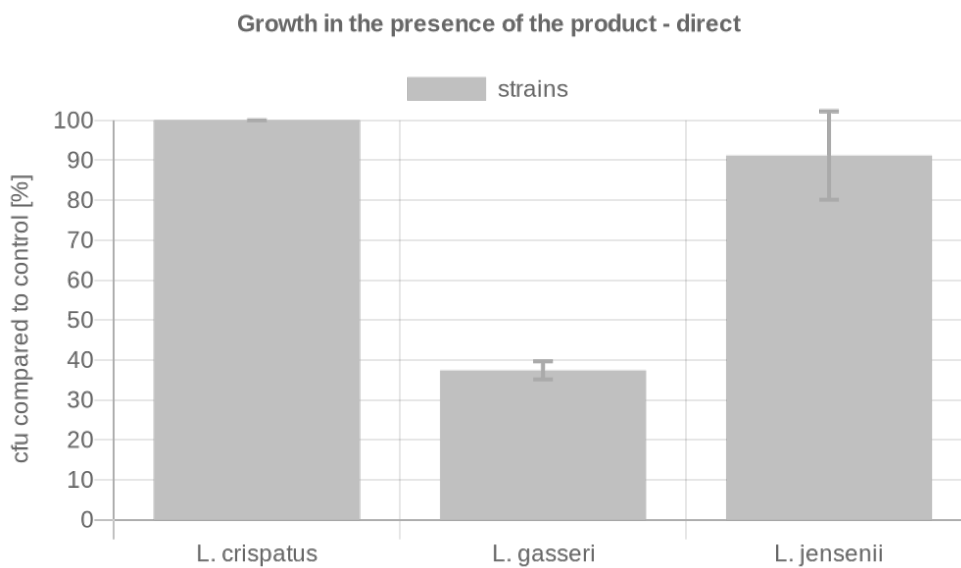


Key-Microbe	t=	4h	Rating
	cfu/ml		
<i>L. crispatus</i>	Control	41933.3	3
	Product	12033.3	
<i>L. gasseri</i>	Control	563.3	1
	Product	773.3	
<i>L. jensenii</i>	Control	260	1
	Product	286.7	
Overall rating:			1.7

Results – VAGINAL -

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.

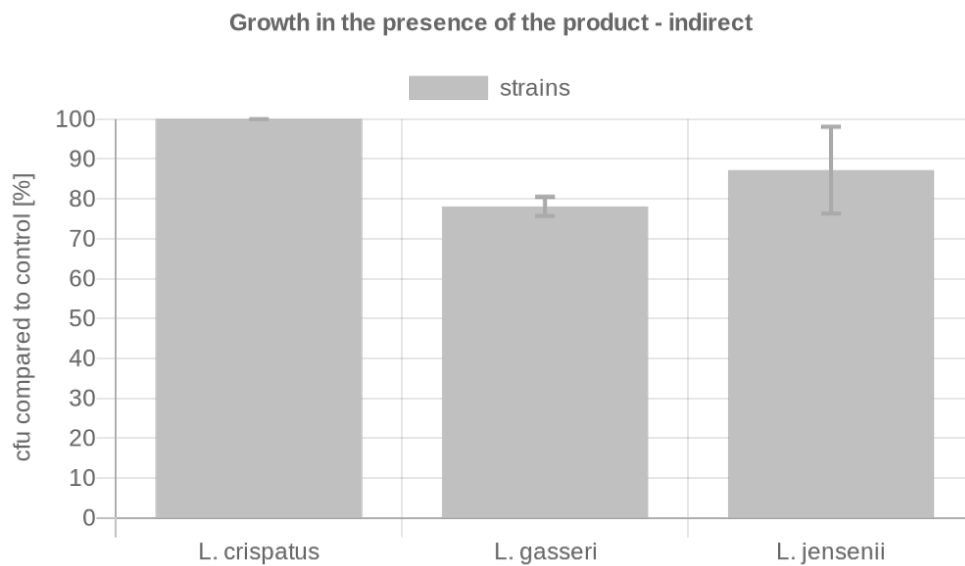


Key-Microbe	cfu/ml		Rating
<i>L. crispatus</i>	Control	100	1
	Product	100	
<i>L. gasseri</i>	Control	841.3	3
	Product	315	
<i>L. jensenii</i>	Control	150.5	2
	Product	137.3	
Overall rating:			2

Results – VAGINAL -

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
	Control	Product	
<i>L. crispatus</i>	Control	100	1
	Product	100	
<i>L. gasseri</i>	Control	640	2
	Product	500	
<i>L. jensenii</i>	Control	156	2
	Product	136	
Overall rating:			1.7

Results

The results are evaluated with grades from 1 (one) to 3 (three).

The product has passed up to grade 2.0.

Here the grade means:

1.0 – 2.0 = Microbiome-friendly | 2.1 – 3.0 = Microbiome-influencing

Test	Grade
Balance of the skin microbiome	1
Diversity of the corresponding skin microbiome (x2)	1.7
Skin-product contact direct (x2)	2
Skin-product contact indirect	1.7
Overall grade	1.7

With an overall grade of 1.7 the seal „Microbiome-friendly“ is awarded according to MyMicrobiome Standard 21.10 Vaginal.

Place, Date: Balzers, 27 November 2023

Responsible person: Dr. Kristin Neumann

Signature:

