

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

Information about the tested product:

Manufacturer:

APOGEPHA Arzneimittel GmbH
Kyffhäuserstraße 27
01309 Dresden
Germany

Name of the product:

FEMALAC[®] Bakterien-Blocker Medizinprodukt Kl. IIa

Product type:	Final product
Application:	Rinse-off
Dilution:	1.25 mg/ml in PBS
Sample received:	14 May 2024
Test Start:	15 May 2024
Test End:	12 June 2024
Test Standard:	MyMicrobiome Standard 25.10 Vulvo-Vaginal
Test result:	1.2
Certification:	granted

Test description

The MyMicrobiome Standard evaluates the influence of cosmetics, personal care products and pharmaceuticals on microbial key players located at specific skin or mucous membrane sites.

An intact vulvo vaginal microbiome has a fundamental influence on female health. Products suitable for the intimate area must also be microbiome-friendly and ensure the maintenance of the balance among the vulvo vaginal microorganisms of the user.

Every person's microbiome is unique. Each body area, however, harbors a characteristic composition of bacteria, viruses and fungi. The test examines the product's influence on the key organisms typical for each body area and thus offers a standardized procedure.

Various aspects are examined:

The microbial quality of the product.

To be evaluated according to our standard, the product needs to be free of contaminants. This is verified in the microbial quality test.

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

The commensal bacterium *Lactobacillus crispatus* is co-cultivated with the pathogenic bacterium *Gardnerella vaginalis*. The co-culture is brought in contact with the product to be tested, which should not disturb the balance between friendly and harmful bacteria.

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

Each body region is colonized by a certain set of microorganisms. For healthy microbiome, it is particularly important to maintain this biodiversity. The influence of the product on the respective microbial composition of the vulvo vaginal area 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 microorganisms in a specific body area, the growth of the individual key organisms should not be influenced by the product. The key organisms of the vulvo vaginal area are brought into direct and indirect contact with the product and their growth is observed.

Results

The microbiological quality of the product.

The prerequisite for the test for microbial friendliness is the microbiological quality of the product based on DIN ISO 17516. The following table contains the limit values for contaminants that must be observed.

Types of organisms	Limit values
Total aerobic microbial count (TAMC) and total combined yeasts/ moulds count (TYMC)	≤ 20 cfu*/g or ml

* colony forming units (cfu)

Results microbiological quality

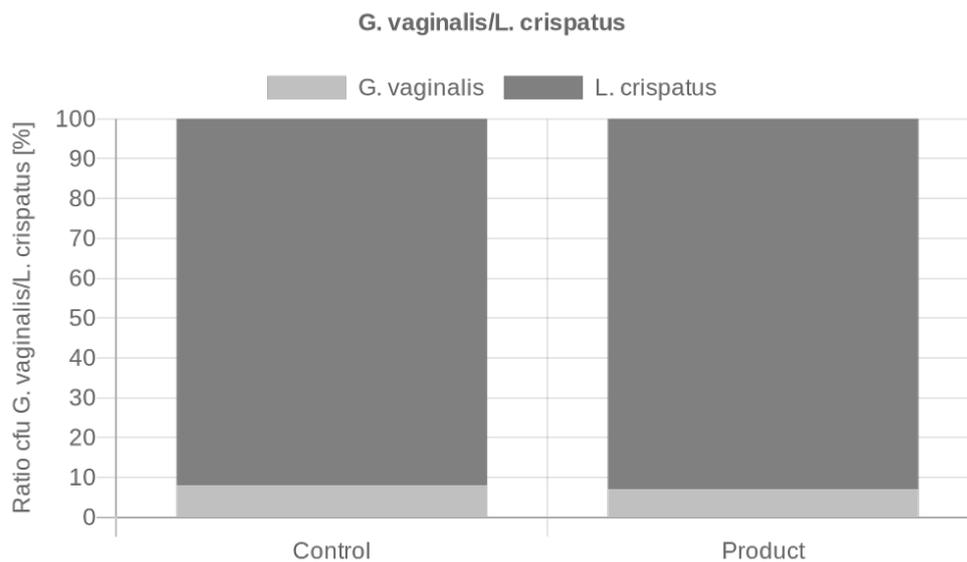
Parameter	Sample no.: 24.881.25.1
TAMC and TYMC [cfu/0,1 ml]	< 20

The microbiological quality of the product is fulfilled.

Results

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

A co-culture of *L. crispatus* and *G. vaginalis* is incubated with the product for 15 min (rinse-off) or 4h (leave-on). Bacterial counts are determined and the cfu ratio of the two bacteria in the presence of the product is assessed and compared to the control sample (PBS).

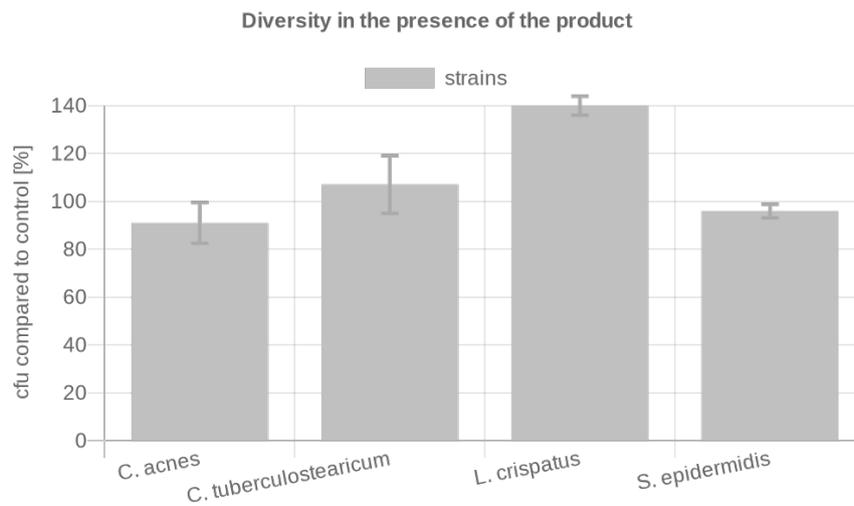


	cfu/ml		Ratio Product/ Control	Grade
	<i>G. vaginalis</i>	<i>L. crispatus</i>		
Control	900	10333.3	1.2	1.0
Product	900	12700		

Results

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

Cultures of the key organisms present in the vulvo vaginal area are incubated with the product for 15 min (rinse-off) or 4h (leave-on). Bacterial colonies are counted, and the cfu ratios in the presence of the product are calculated in % relative to the control sample (PBS).

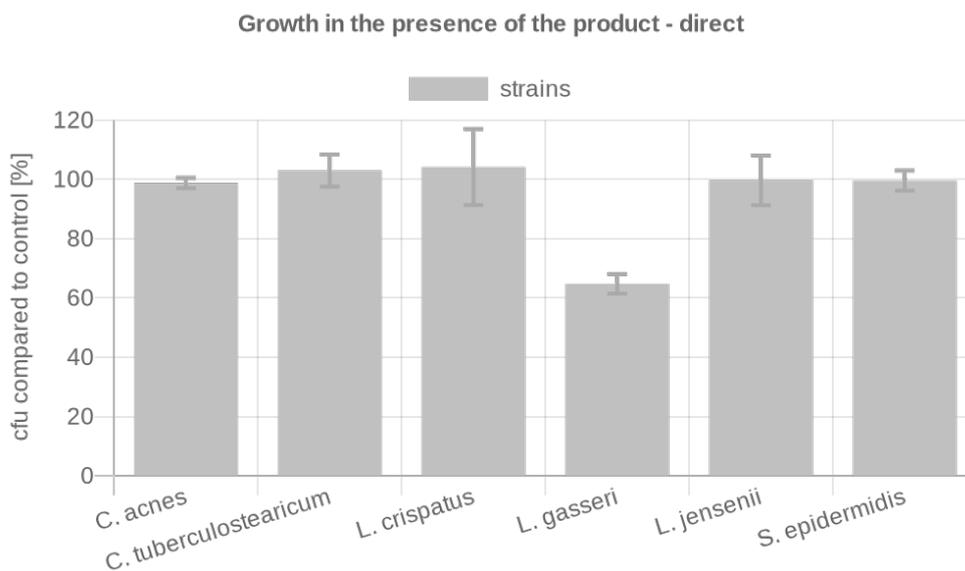


Key-Microbe	t=	15min	Rating
	cfu/ml		
<i>C. acnes</i>	Control	586,7	1
	Product	533,3	
<i>C. tuberculostearicum</i>	Control	466,7	1
	Product	500	
<i>L. crispatus</i>	Control	10733,3	1
	Product	15000	
<i>S. epidermidis</i>	Control	890	1
	Product	856,7	
Overall rating:			1.0

Results

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

The influence of the product on the growth of each individual key organism of the vulvo vaginal area is investigated and the cfu ratio in the presence of the product is calculated in % relative to the control sample (PBS). Product contact with microorganisms is direct.



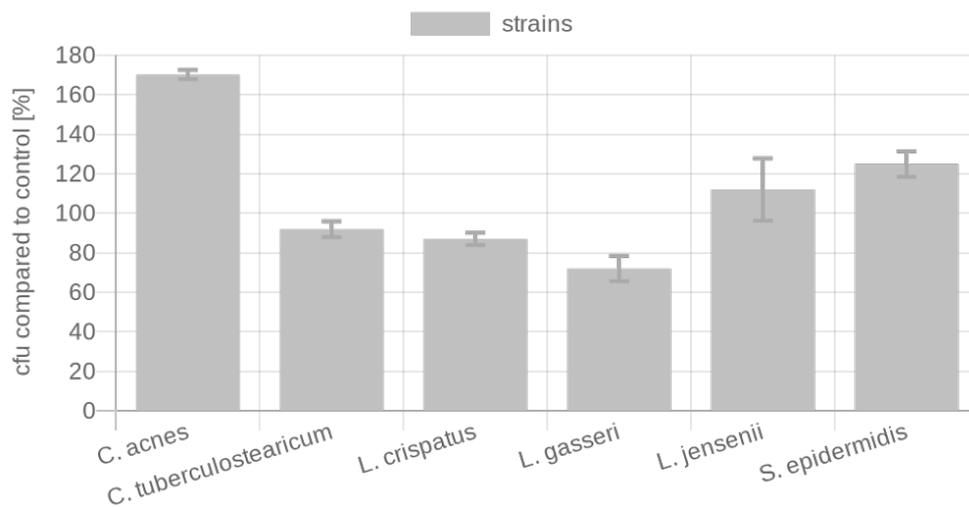
Key-Microbe	cfu/ml		Rating
C. acnes	Control	605.7	1
	Product	598.5	
C. tuberculoostearicum	Control	1144	1
	Product	1178.7	
L. crispatus	Control	2253.7	1
	Product	2349	
L. gasseri	Control	524.3	3
	Product	340	
L. jensenii	Control	132.7	1
	Product	132.3	
S. epidermidis	Control	252	1
	Product	251	
Overall 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 key organism of the vulvo vaginal area is investigated and the cfu ratio in the presence of the product is calculated in % relative to the control sample (PBS). Product contact with microorganisms is indirect.

Growth in the presence of the product - indirect



Key-Microbe	cfu/ml		Rating
C. acnes	Control	288.3	3
	Product	490.7	
C. tuberculoostearicum	Control	1149.3	2
	Product	1056	
L. crispatus	Control	2585.3	2
	Product	2250	
L. gasseri	Control	559	2
	Product	402.7	
L. jensenii	Control	25	1
	Product	28	
S. epidermidis	Control	270.3	1
	Product	337.5	
Overall rating:			1.8

Results

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

The product has passed if it obtains grades between 1.0 and 2.0.

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

Test	Grade
Balance of the vaginal microbiome	1.0
Diversity of the corresponding microbiome (x2)	1.0
Product contact direct (x2)	1.3
Product contact indirect	1.8
Overall grade	1.2

With an overall grade of 1.2 the seal „Microbiome-friendly“ is awarded according to MyMicrobiome Standard 25.10 Vulvo-Vaginal.

Place, Date: Balzers, 29 July 2024

Responsible person: Dr. Kristin Neumann

Signature:

