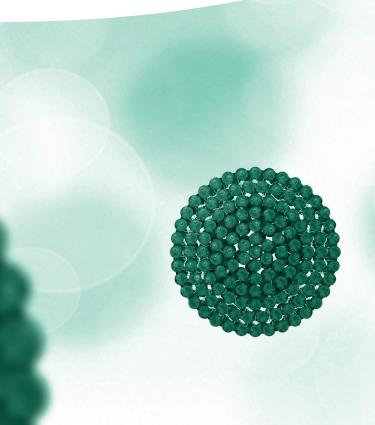


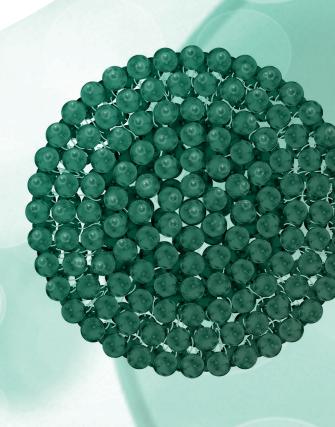


# **PATCH TEST**

**EXO DDS Bakuchiol 10%** 

REF.1







## 1. TYPE OF CLINICAL STUDY

Safety test on healthy adult volunteers, with 2 parallel administration sites, to verify the good compatibility of the product, **EXO DDS Bakuchiol 10% REF. 1**, after a single application, on the skin of the back and under a semi-occlusive patch for 48 hours and with a re-evaluation after 96 hours.

SKIN COMPATIBILITY OF THE PRODUCT EXO DDS Bakuchiol, 10% REF. 1:

#### SIMPLE SINGLE PATCH TEST

#### 2. PRODUCT DESCRIPTION

**Product:** EXO DDS Bakuchiol 10% REF. 1

**INCI:** 

AQUA, POLYGLYCERYL-10 LAURATE, GLYCERIN, PROPANEDIOL,

PHOSPHATIDYLCHOLINE, METHYLPROPANEDIOL, BAKUCHIOL, COCO-BETAINE,

PERSEA GRATISSIMA FRUIT EXTRACT, BUTYL AVOCADETE, MALTODEXTRIN,

SODIUM COCOYL ISETHIONATE, CAPRYLYL GLYCOL, BETASITOSTEROL, CITRIC ACID,

PHENYLPROPANOL, COCOS NUCIFERA OIL, SODIUM ISETHIONATE, TOCOPHEROL

Manufacturer: Nanovex Biotechnologies S.L.

### 3. CLASSIFICATION ACCORDING TO PRIMARY IRRITATION INDEX

The Primary Irritation Index (PII) is calculated according to the data obtained in the test. The value of the resulting PII is used to classify the product according to the following table:

PII = Σ the degree of erythema and edema

Volunteer number

## 4. FINAL REPORT

Clinical safety study in healthy adult volunteers for verification of good skin compatibility of the product:

EXO DDS Bakuchiol_01	BATCH: VEXAVOBAK_240611	Simple Single Patch Test
_		

PII	CLASSIFICATION			
PII = 0	NON IRRITANT	Very good skin compatibility		
PII < 0,2	NON IRRITANT	Good skin compatibility		
0,2 ≤ PII < 0,5	MILDLY IRRITATING	Intermediate skin compatibility		
0,5 ≤ PII < 1	MODERATELY IRRITATING	Poor skin compatibility		
PII ≥ 1	VERY IRRITANT	Very poor skin compatibility		





The table below shows the results obtained after a single application of the product, **EXO DDS Bakuchiol 10% REF. 1**, by healthy adult volunteers. The determination of the Primary Skin Irritation Index (P.S.I.I.) corresponds to the mean of the weighted sum of the scores obtained in the panel as a whole:

N° Vol.	Age	Sex*	Phototype	Skin type**	Erythema	Edema
1	22	F	III	S	0	0
2	43	М	III	N	0	0
3	52	F	III	S	0	0
4	61	М	III	S	0	0
5	18	М	III	N	0	0
6	36	F	IV	N	0	0
7	40	М	II	S	0	0
8	55	F	III	N	0	0
9	28	F	III	S	0	0
10	30	F	IV	N	0	0

<sup>\*</sup> SEX: F/Female M/Male

## 6. CONCLUSIONS

The conclusions of the clinical study carried out for the verification of good skin compatibility for the product, **EXO DDS Bakuchiol 10% REF. 1**, in healthy adult volunteers, using **SIMPLE SINGLE PATCH TEST**, were as follows:

- The product, **EXO DDS Bakuchiol 10%**, **BATCH: VEXAVOBAK\_240611**, did not produce an irritant response in any of the volunteers.
- The product, **EXO DDS Bakuchiol 10% BATCH: VEXAVOBAK\_240611**, was **NON IRRITANT**.

As of the date of this report, and according to the results obtained in the study carried out under the experimental conditions adopted, it can be concluded that the product, **EXO DDS Bakuchiol 10% REF. 1** has

#### "VERY GOOD SKIN COMPATIBILITY"

Likewise, it is confirmed that the product, **EXO DDS Bakuchiol 10% REF. 1**, has been

#### "TESTED UNDER DERMATOLOGICAL CONTROL"



<sup>\*\*</sup> SKIN TYPE: S/Sensitive N/Normal