

12/12/2013

**FLEBION 50**  
**GALENIA SKIN CARE ANTI-REDNESS CREAM SPF 50**

**GALENIA BIOTECNOLOGIE SRL**

## COMPOSITION

**Functional substances:** Shea butter 1%, hesperidin 1%, olive oil 1%, rutin 1%, vitamin E 1%, bioflavonoids orange 0.5%, bisabolol 0.2%, cholesterol 0.2%, ceramides 0.1%, escin, beta-sitosterol and phospholipids complex 0.1%, serine 0.1%.

**Sun filters :** Ethylhexyl methoxycinnamate (UV-B filter) 10%, octocrylene (UV-B filter) 8%, butyl methoxydibenzoylmethane (UV-A filter) 5%, titanium dioxide (UV-A and UV-B filter) 4.5%, ethylhexyl triazone (UV-B filter) 4%.

INCI UE	INCI USA	Functionality (*)	CAS	EINECS	
aqua	water	solvent	7732-18-5	231-791-2	
ethylhexyl methoxycinnamate	ethylhexyl methoxycinnamate	sunscreen agent	5466-77-3	226-775-7	
octocrylene	octocrylene	sunscreen agent	6197-30-4	228-250-8	
butyl methoxydibenzoylmethane	butyl methoxydibenzoylmethane	sunscreen agent	70356-09-1	274-581-6	
titanium dioxide	titanium dioxide	colorant	13463-67-7	236-675-5	
ethylhexyl triazone	ethylhexyl triazone	sunscreen agent	88122-99-0	/	
cetyl palmitate	cetyl palmitate	skin-conditioning agent-occlusive	540-10-3	208-736-6	
dimethicone	dimethicone	skin-conditioning agent-occlusive	141-63-9	205-492-2	
butylene glycol	butylene glycol	skin conditioning agent-miscellaneous	107-88-0	203-529-7	
glycol stearate	glycol stearate	skin conditioning agent-emollient	111-60-4	203-886-9	
steareth-21	steareth-21	surfactant-emulsifying agent	9005-00-9	/	
butyrospermum parkii butter	butyrospermum parkii (shea) butter	skin conditioning agent-miscellaneous	194043-92-0	293-515-7	
hesperidin	hesperidin	flavoring agent	520-26-3	208-288-1	
olea europaea fruit oil	olea europaea (olive) fruit oil	skin-conditioning agent-occlusive	8001-25-0	232-277-0	
rutin	rutin	skin conditioning agent-miscellaneous	130603-71-3	205-814-1	
tocopheryl acetate	tocopheryl acetate	antioxidant	58-95-7	231-710-0	
behenyl alcohol	behenyl alcohol	binder	661-19-8	211-546-6	
bioflavonoids	bioflavonoids	skin conditioning agent-miscellaneous	61788-55-4	/	
maltodextrin	maltodextrin	skin conditioning agent-miscellaneous	9050-36-6	232-940-4	
bisabolol	bisabolol	skin conditioning agent-miscellaneous	23089-26-1	/	
cholesterol	cholesterol	skin conditioning agent-miscellaneous	57-88-5	200-353-2	
hexyldecanol	hexyldecanol	skin conditioning agent-emollient	2425-77-6	219-370-1	
ceramide 3	ceramide 3	skin conditioning agent-miscellaneous	100403-19-8	309-560-3	
phospholipids	phospholipids	skin conditioning agent-miscellaneous	123465-35-0	/	
escin	escin	not reported	6805-41-0	229-880-6	
beta-sitosterol	beta-sitosterol	skin conditioning agent-miscellaneous	83-46-5	201-480-6	
serine	serine	skin conditioning agent-miscellaneous	56-45-1	200-274-3	
triacontanyl PVP	triacontanyl PVP	film former	136445-69-7	/	
phosphatidylcholine	phosphatidylcholine	skin conditioning agent-miscellaneous	8002-43-5	232-307-2	
carthamus tinctorius seed oil	carthamus tinctorius (safflower) seed oil	antioxidant	8001-23-8	232-276-5	

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helianthus annuus seed oil	helianthus annuus (sunflower) seed oil	skin conditioning agent-miscellaneous	164250-88-8	232-273-9
potassium cetyl phosphate	potassium cetyl phosphate	surfactant-emulsifying agent	17026-85-6	242-768-1
urea	urea	skin conditioning agent-humectant	57-13-6	200-315-5
PEG-8 stearate	PEG-8 stearate	surfactant-emulsifying agent	70802-40-3	/
diethylhexylcyclohexane	diethylhexylcyclohexane	skin-conditioning agent-occlusive	100182-46-5	283-854-9
parfum	fragrance	fragrance ingredient	/	/
glyceryl stearate	glyceryl stearate	skin conditioning agent-emollient	85666-92-8	250-705-4
carbomer	carbomer	emulsion stabilizer	76050-42-5	/
triethanolamine	triethanolamine	pH adjuster	102-71-6	203-049-8
disodium EDTA	disodium EDTA	chelating agent	139-33-3	205-358-3
BHT	BHT	antioxidant	128-37-0	/
alcohol denat.	alcohol denat.	solvent	64-17-5	200-578-6
ascorbyl palmitate	ascorbyl palmitate	antioxidant	137-66-6	205-305-4
tocopherol	tocopherol	antioxidant	10191-41-0	/
phenoxyethanol	phenoxyethanol	preservative	122-99-6	204-589-7
ethylhexylglycerin	ethylhexylglycerin	skin conditioning agent-miscellaneous	70445-33-9	/
tropolone	tropolone	not reported	/	/
CI 42090	blue 1	colorant	3844-45-9	/
CI 19140	yellow 5	colorant	1934-21-0	/
CI 14700	red 4	colorant	4548-53-2	224-909-9

- (\*) The functions listed are not intended to represent the only function an ingredient may perform, and do not preclude the assignment of additional functions. They refer to the last edition of "International Cosmetic Ingredient and Dictionary Handbook".

- The percentage of possible allergens present in the formulation as constituents of some substances (mostly perfumes and essential oils) has not to be added up to that of other ingredients, since it would be counted twice.

- During the production process, the formulation above may be slightly changed in terms of percentages of some raw materials, in order to guarantee regularly the conformity with reference standards. Such variations do not affect the functional characteristics and the safety of the final product.

## CMR substances

This product does not contain CMR substances.

## Nanomaterials

This product does not contain nanomaterials.

## COMPULSORY WARNINGS to be printed on the label

Taking into consideration substances contained in the product, there is no need to label particular warnings.

## CATEGORY

(As defined on Cosmetic Products Notification Portal ("CPNP") according to the new Regulation (EC) n.1223/2009).

Skin products // Sun and self-tanning products // Sun protection products

## SHELF LIFE

The shelf life of the product must be defined on the basis of the stability study carried out on the finished product in its primary package. However, taking into account experience of Biofarma on similar formulations and considering the best workable conditions of packing, we think

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that the product may have a validity of no more than months<sup>24</sup>. This information has to be considered as a guide because it is defined on theoretical basis. It has to be confirmed by a stability study which will be carried out strictly after explicit request of the Responsible Person and agreement on the relative quotation.

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### **PaO (Period After Opening)**

The period of validity after opening should be defined on the basis of a study that considers all significant aspects. However, taking into account experience of Biofarma on similar formulations and considering the best workable conditions of packing, we think that the product may have a PAO of no more than 6 months. This information has to be considered as a guide because it is defined on theoretical basis. It has to be confirmed by a study which will be carried out strictly after explicit request of the Responsible Person and agreement on the relative quotation. It is to remind that the followings are excluded from the PaO: single use products (in single use packaging) and products in a container in which there is no possibility of contact between the product and the external environment (eg, sealed pressurized containers).

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### **STORAGE**

The product must be stored at a temperature between 10°C and 25°C, in a dry place and protected from light and from heat located sources

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### **NOTE**

- *The use on the packaging materials of the registered trademarks of the raw materials must be previously agreed with the supplier (trade mark license contract)*
- *The percentage of the functional substances is ensured at the time of production.*