

7531000G – MYRICELINE™ SPE 90

Version: 25 - 24/AUG/2015

1. PRODUCT IDENTIFICATION

Trade Name:	MYRICELINE™ SPE 90
Manufacturer:	PROVITAL
Responsible for the Safety Assessment:	Lourdes Mayordomo
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Kind of Raw Material:	Active Ingredient
Function of the Ingredient (PCPC Inventory):	Skin-Conditioning Agents - Miscellaneous.
Function of the Ingredient (UE Inventory):	Skin Conditioning
INCI approved in:	Registered in EU, USA, Japan
Japanese Name:	JCLS:---- Japanese translation available in PCPC.

2. PRODUCT COMPOSITION**Components Breakdown (INCI). Including actives, solvents, preservatives, antioxidants and other additives:**

[EU]		CAS	EINECS
Dihydromyricetin	100 %	84929-34-0	284-518-4
		27200-12-0	---

PCPC [CTFA]		CAS	EINECS
Dihydromyricetin	100 %	27200-12-0	---

Impurities:

Heavy Metals (as Pb)	Less than 20 ppm.
Pesticides	No data available. Not expected to be found.

3. TOXICOLOGICAL INFORMATION**Data obtained in our own toxicological tests and/or bibliographical research****Animal testing:**

This product has not been the subject of animal testing or retesting for cosmetic purposes by or on behalf of this company.

General information:

No data available.

Classification according to Council of Europe (*):

Non-classified.

*(1)- Non-recommended ingredients (2)-Ingredients which could not be assessed (3) –Recommended ingredients

Cytotoxicity:

Test performed with other products of Provital: The studies of toxicity realized to determine the safety of the product MYRICELINE (Cod.75340) were carried out with the active Dihydromyricetin at a purity of 70 %. Neutral Red Releasing Method on SIRC cell line ,Results: CI50 >50%, % of mortality at dilution 50%= 42.0. Unimportant cytotoxicity

Skin Irritation:

Test performed with other products of Provital: The studies of toxicity realized to determine the safety of the

product MYRICELINE (Cod.75340) were carried out with the active Dihydromyricetin at a purity of 70 %. It was tested at 2%. Patch Test on 10 volunteers, Index of Primary Cutaneous Irritation = 0.10, Well Tolerated

Skin Sensitization:

Test performed with other products of Provital: The studies of toxicity realized to determine the safety of the product MYRICELINE (Cod.75340) were carried out with the active Dihydromyricetin at a purity of 70 %. It was tested at 2%.RIPT Test on 52 Volunteers, no pathological irritation, nor sensitisation reaction significant of cutaneous intolerance was noted

Eye Irritation:

Test performed with other products of Provital: The studies of toxicity realized to determine the safety of the product MYRICELINE (Cod.75340) were carried out with the active Dihydromyricetin at a purity of 70 %. It was tested at 2%. In-vitro Irritation Index: HET-CAM :4.6

Mutagenicity:

Test performed with other products of Provital: The studies of toxicity realized to determine the safety of the product MYRICELINE (Cod.75340) were carried out with the active Dihydromyricetin at a purity of 70 %. Ames Test on Salmonella TA1535, TA1537, TA98, TA100, TA102, with and without S9, Results: negative , the substance did not show mutagenic activity

Acute toxicity:

Dihydromyricetin (RTECS n° DJ2982375): LD p.o. mouse > 5 g/Kg; LD50 i.p. mouse= 1410 mg/kg

Subchronic and chronic toxicity:

Dihydromyricetin: hepatoprotective activity against CC14-toxicity in rats, D-GalN in mice and against CC14-toxicity in primary cultured rat hepatocytes (Bio. Pharm. Bull. 1997 Apr; 20(4):381-5

Reproductive effects:

No data available.

Other data:

Dihydromyricetin: anticancer effects on several human cancer cell lines in vitro and on transplant mouse B16 melanoma in vivo. (Ai Zheng 2003 Ap 5, 22(4): 363-367)

4. ECOLOGICAL DATA**Biodegradability:**

No data available.

Aquatic Toxicity:

No data available.

Other data:

No data available.

5. CONCLUSION

The components of this product have registered adverse effects neither in its described uses nor in the historical marketing of this company. These data and the available toxicological information lead to the conclusion that the use of this product, under the normal conditions of cosmetic use, involves no risk for consumers.

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