

## 7310000G – TANOSITOL™ SPE

Version: 22 - 24/AUG/2015

### 1. PRODUCT IDENTIFICATION

<b>Trade Name:</b>	TANOSITOL™ SPE
<b>Manufacturer:</b>	PROVITAL
<b>Responsible for the Safety Assessment:</b>	Lourdes Mayordomo
<b>Tf./Fax:</b>	3493-7192350/7190294
<b>e-mail:</b>	<a href="mailto:l.mayordomo@provitalgroup.com">l.mayordomo@provitalgroup.com</a>
<b>Kind of Raw Material:</b>	Active Ingredient
<b>Function of the Ingredient (PCPC Inventory):</b>	Hair Conditioning Agent, Humectants
<b>Function of the Ingredient (UE Inventory):</b>	Antistatic, Hair Conditioning Agent, Humectant
<b>INCI approved in:</b>	Registered in EU, USA, Japan
<b>Japanese Name:</b>	JCLS:---- Japanese translation available in PCPC.

### 2. PRODUCT COMPOSITION

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

[EU]		CAS	EINECS
Inositol*	100 %	643-12-9	211-394-0
		87-89-8	201-781-2
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PCPC [CTFA]		CAS	EINECS
Inositol*	100 %	643-12-9	211-394-0
		87-89-8	201-781-2

<b>Impurities:</b>	
<b>Heavy Metals (as Pb)</b>	Less than 20 ppm.
<b>Pesticides</b>	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:**

TANOSITOL SPE (Cod. 7310): Neutral Red Releasing Method on SIRC cell line ,Results: CI50 >50%, % of mortality at dilution 50%= 0. Negligible cytotoxicity

**Skin Irritation:**

TANOSITOL SPE (Cod. 7310) at 5%: Patch Test on 10 volunteers, Index of Primary Cutaneous Irritation = 0.10, Good cutaneous compatibility

**Skin Sensitization:**

TANOSITOL SPE (Cod. 7533) at 5%: RIPT Test on 53 Volunteers, no pathological irritation, nor sensitisation reaction significant of cutaneous intolerance was noted

**Eye Irritation:**

TANOSITOL SPE (Cod. 7533):In-vitro Irritation Index: HET-CAM (con.5%) :3.5

**Mutagenicity:**

TANOSITOL SPE (Cod. 7310): Ames Test on Salmonella TA1535, TA1537, TA98, TA100, TA102, with and without S9, Results: negative , the substance did not show mutagenic activity

**Acute toxicity:**

No data available.

**Subchronic and chronic toxicity:**

No data available.

**Reproductive effects:**

D-Chiro-inositol: Studies in rats and rabbits at doses up to 2000 mg/kg/day, no adverse effects on mating,fertility or embryo/fetal development have been found(Human Reproduction,17(9),2451-258,2002)

**Other data:**

TANOSITOL SPE (Cod. 7310): This product has not UV absorption then it has not photoreactive potential

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**4. ECOLOGICAL DATA****Biodegradability:**

No data available.

**Aquatic Toxicity:**

No data available.

**Other data:**

No data available.

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**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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