7240000G – VITASOURCE™

Version: 24 - 24/AUG/2015

1. PRODUCT IDENTIFICATION

Trade Name:	VITASOURCE™
Manufacturer:	PROVITAL
Responsible for the Safety Assessment:	Lourdes Mayordomo
Tf./Fax:	3493-7192350/7190294
e-mail:	l.mayordomo@provitalgroup.com
Kind of Raw Material:	Active Ingredient
Function of the Ingredient (PCPC Inventory):	Antioxidants; Skin-Conditioning Agents-Miscellaneous
Function of the Ingredient (UE Inventory):	Antioxidant; Skin conditioning
INCI approved in:	Registered in EU, USA
Japanese Name:	---

2. PRODUCT COMPOSITION

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

[EU]		CAS	EINECS
Propanediol	90 - 97 %	504-63-2	207-997-3
		26264-14-2	
Aqua	0,5 - 9,5 %	7732-18-5	231-791-2
Baicalin	0,7 - 1,5 %	94279-99-9	304-845-9
		21967-41-9	---
		314041-17-3	---
Preservatives			
none	0 %	---	---

PCPC [CTFA]		CAS	EINECS
Propanediol	90 - 97 %	504-63-2	207-997-3
		26264-14-2	
Water	0,5 - 9,5 %	7732-18-5	231-791-2
Baicalin	0,7 - 1,5 %	21967-41-9	---
		314041-17-3	---
Preservatives			
none	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:

American Herbal Products Association: Scutellaria baicalensis root - Herbs that can be safely consumed when

used appropriately (Class 1)

Classification according to Council of Europe (*):

Not classified

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

Cytotoxicity:

VITASOURCE (Cod. 72400): Neutral Red Release Assay performed using SIRC cell line. Results: CI50>50%, % of mortality at dilution 50% = 29%. Unimportant cytotoxicity.

Skin Irritation:

VITASOURCE (Cod.72400): Patch Test on 10 volunteers, occlusive patch for 48 hours, product tested at 25%. No irritant reactions were registered at 15 minutes and 24 hours after patch removal. The clinical cutaneous compatibility of this product may be judged "Very Good"

Propanediol (RTECS no. TY2010000, Last Updated:200608): Standard Draize Test in human skin, product at 100% for 48 hours and 7 days, moderate

Propanediol. Skin irritation tests in NZW rabbit: undiluted product at 0.5ml was considered to be a Slight irritant. (Supplier data)

Skin Sensitization:

VITASOURCE (Cod. 72400). Marzulli and Maibach's Method: Human Repeated Insult Patch Test. Study on 53 volunteers, product tested at 25%. No pathological irritation, nor sensitisation reaction was registered. Vitasource is classified as a No-Sensitizant product.

Propanediol. Skin sensitization tests: Studies performed in guinea pigs by Landsteiner/Draize method and by Magnusson-Kligman method considered the product to be non-sensitizing. Studies in human at product concentration of 50% in 112 volunteers and 75% in 207 volunteers considered the product not to be a primary skin irritant or a sensitizing agent. (Supplier data)

Eye Irritation:

VITASOURCE (Cod. 72400): The Hen's Eggs Test on the Chorioallantoic Membrane (HET-CAM), product tested at 25%, Mean Irritation Index = 2.0. The trial product can be considered as WELL TOLERATED at the ocular level.

Propanediol. Eye irritation tests in NZW rabbit: undiluted product at 0.1ml was considered to be Non-irritating and at 0.2 ml was considered to be Practically non-irritating. (Supplier data)

Mutagenicity:

VITASOURCE (Cod. 72400): Genic Mutation Bacteria In Vitro Test (Ames Test), using 5 strains of Salmonella typhimurium (TA1535, TA1537, TA98, TA100 and TA102), both in the presence and absence of metabolic activation system (S-9). The product was tested at five dose levels between 0.0032 and 0.05 mg/plate. No significant increase in the number of revertants was noted in any of the strains. The trial product can be considered as: No mutagenic.

Propanediol. Genetic toxicity tests: This product was considered non-mutagenic in the Ames Test (OECD method no.471), in the HPRT Test (OECD method no. 476), in the chromosome aberrations test (OECD method no.473) and in the in vivo mouse micronucleus test (92/69/EEC Method) (Supplier data)

Acute toxicity:

Crude drug extract from Scutellaria baicalensis (RTECS no. RI5948540): TDLo p.o. rat = 200 mg/kg

Baicalin (RTECS no. LZ5776910): TDLo p.o. mouse= 15 mg/kg, LD50 i.t. rat = 11g/kg, TDLo i.p. mouse = 50 mg/kg, TDLo i.p. mouse = 100 mg/kg

Several studies of the acute toxicity of various preparations from the root of Scutellaria baicalensis concluded that such preparations have very low toxicity when given orally. (Adverse Effects of Herbal Drugs, vol. 2, pp 291, Springer-Verlag Berlin Heidelberg 1993)

Baicalin was reported to have an intraperitoneal LD50 of 3 g/kg in mice. (Adverse Effects of Herbal Drugs, vol. 2, pp 291, Springer-Verlag Berlin Heidelberg 1993)

Propanediol (RTECS no.TY2010000, Last Updated:200608): LDLo p.o rat = 10g/kg, LDLo i.m. rat = 6 g/kg, LD50 i.p. mice = 4780 mg/kg, LDLo p.o cat = 3 g/kg, LDLo i.v. rabbit = 3 g/kg, LD50 p.o mice = 4500 mg/kg

Propanediol. Acute toxicity tests: p.o. in rat LD50 = 15800 mg/kg, dermal in rat LD50 > 4200 mg/kg and inhalation in rat, DL > 5000 mg/m3. (Supplier data)

Subchronic and chronic toxicity:

Crude drug extract from Scutellaria baicalensis (RTECS no.RI5948540): TDLo p.o. rabbit= 175 mg/kg/5D-C

Baicalin (RTECS no. LZ5776910): TDLo p.o. mouse= 180 mg/kg/12D-I, TDLo i.p. rat = 2.5 mg/kg/5D-I

An effective part isolated from Scutellaria baicalensis (RTECS no.LZ5776910): TDLo p.o. mouse= 2350

mg/kg/47D-I

Scutellaria baicalensis, extract (RTECS no.VR6060050): TDLo p.o. mouse= 12 ml/kg/12D, TDLo p.o mouse = 2.1 g/kg/7D-I

90-day oral toxicity study in rats was realized with a standardized plant composition, with baicalin from the roots of Scutellaria baicalensis and catechin from the Acacia catechu. Four groups of animals (10 males and females per group) of dose levels of 250, 500, and 1000 mg/kg/day, as well as a control (0.5% carboxymethylcellulose) were tested. A dose of 1000 mg/kg/day was identified as the NOAEL in this study. (Food Chem Toxicol. 2010, May; 48(5):1202-9.)

Propanediol. Repeat-Dose Toxicity tests: p.o. in rat for 90 days NOEL = 1000 mg/kg/day and inhalation in rat after 9 exposures NOEL= 1800 mg/m3. (Supplier data)

Reproductive effects:

An aqueous extract of Scutellaria baicalensis administered subcutaneously to female mice for 5 days, did not caused decrease fertility. (Adverse Effects of Herbal Drugs, vol. 2, pp 293, Springer-Verlag Berlin Heidelberg 1993)

This study aims to evaluate the effects of S.baicalensis aqueous root extract on embryonic development in mice. Pregnant mice were randomly divided into a four groups. The oral doses were: 2, 8 and 32 g/kg/day from gestation day 6 to15. The parameters evaluated were: live and dead fetuses, resorptions, external and skeletal malformed fetuses, maternal body weight, maternal liver, kidneys, and heart weights. There was no significant difference in fetal parameters among groups. The study concluded that oral administration of the product at or below 32 g/kg/day to mice during organogenesis did not cause significant fetal external or skeletal malformations. However, 32 g/kg/day presented potential maternal toxicity. (Birth Defects Res B Dev Reprod Toxicol. 2009, Apr; 86(2):79-84.)

Propanediol. Prenatal development toxicity test in rat (OECD method no. 414), the product administered at 250 and 1000 mg/kg by oral gavage on gestation days 6-15, was considered non-toxic. Study on effects during reproduction in rats after a 90-day oral administration, there were no effects to reproductive organs and differences in fertility. (Supplier data)

Other data:

VITASOURCE (Cod. 72400):Study on the frequency of spontaneous transformation in mouse fibroblasts (NIH-3T3). No transforming effects were detected, so Vitasource registered no tumerogenic potential.

It was studied the anticancer in vitro and in vivo activity of Sctuellaria baicalensis on head and neck squamous cell carcinoma (HNSCC). Two human HNSCC cell lines (SCC-25 and KB) and a nontumorigenic cell line (HaCaT) were tested. Scutellaria demonstrated a strong growth inhibition in both tested human HNSCC cell lines and no growth inhibition of HaCaT cells were observed; la IC 50 were 150ug/ml. The in vivo test were performed in mice with inoculation of KB cells and treated with Scutellaria at 75 mg/kg p.o. for 7 weeks. A 66% reduction in tumor mass was observed was observed in nude mice. (J Cancer Research 63, 4037-4043, 2003)

4. ECOLOGICAL DATA

Biodegradability:

Propanediol: BOD5 = 1160000 mg/L (Supplier data)

Aquatic Toxicity:

Propanediol. Acute toxicity tests: Fish (Pimephales promelas) LC50 = 7417 mg/L, Daphnia magna EC50 = 7417 mg/L and growth inhibition of algae EC50 > 10000 mg/L (Supplier data)

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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