# 7170000G – AFFIPORE™

*Version: 25 - 24/APR/2026*

## 1. PRODUCT IDENTIFICATION

| | |
|---|---|
| **Trade Name:** | AFFIPORE™ |
| **Manufacturer:** | PROVITAL, S.A.<br>P.I. CAN SALVATELLA<br>08210 BARBERÀ DEL VALLÈS<br>BARCELONA (SPAIN)<br>e-mail: info@weareprovital.com<br>Tf: + 34 -937192350 |
| **Kind of Raw Material:** | Active Ingredient |
| **Function of the Ingredient (PCPC Inventory):** | Skin-Conditioning Agents - Miscellaneous |
| **Function of the Ingredient (UE Inventory):** | Perfuming, Skin conditioning |

## 2. PRODUCT COMPOSITION

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

| [EU] | | CAS | EC |
|---|---|---|---|
| Butylene Glycol | 96 - 98 % | 107-88-0<br>6290-03-5 | 203-529-7<br>228-532-0 |
| Barosma Betulina Leaf Extract | 2 - 4 % | 84649-93-4 | 283-474-3 |
| Additives | | | |
| Citric Acid | 0,05 - 0,25 % | 77-92-9<br>5949-29-1 | 201-069-1 |

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| PCPC [CTFA] | | CAS | EC |
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## 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:**

Buchu leaves are considered by the FDA as Foof Addtives permitted for direct addition to food for human consumption. Natural flavoring substances and natural substances used in conjunction with flavors. (21CFR172.510)

Pulegone is one of the characteristic components of Buchu essential oil. In some opinions of the CIR (Cosmetic Ingredient Review) from other plants which also contain pulegone, it is indicates that cosmetic ingredients are safe with pulegone levels below 1%. AFFIPORE meets this requirement.

There is a CIR Final Report on Safety Assessment including all the toxicological data of Butylene Glycol (IJT 25(S2), 2006)

Citric acid is naturally present in common fruit and vegetables, and consequently there is a long history of human exposure. In addition, Citric Acid has well established and documented metabolic pathways in humans. (WHO Food Additives, Series 5, 1973). There is no documented human evidence to suggest that citric acid is either a reproductive or developmental toxicant; this is also substantiated by the animal studies that have been conducted. Therefore, no classification for reproductive and developmental toxicity is required according to Regulation (EC) No 1272/2008. (ECHA-REACH Registration Dossier).

The CIR Expert Panel concluded that Citric Acid is safe in the present practices of use and concentration described in this safety assessment. (IJT 33(Suppl.2):16-46, 2014)

**Cytotoxicity:**

AFFIPORE (Cod.71700) at 15%: Neutral Red Release Assay performed using SIRC cell line. Results: CI50>50%, % of mortality at dilution 50% < 20%. Negligible cytotoxicity.

Evaluation of an extract of Barosma betulina using the microculture tetrazolium (MTT) cellular viability assay on transformed human kidney epithelium cells. The extract was considered not toxic at the concentrations tested and had IC50 values > 100µg/ml. (South African Journal of Botany, 73(4), 2007, 588:592)

**Skin Irritation:**

AFFIPORE (Cod.71700): Patch Test on 13 volunteers, occlusive patch for 48 hours. Product tested at 15%. The average irritant score of the product is 0.00. Under these conditions, the product AFFIPORE can be considered as non-irritant regarding its primary skin tolerance.

Undiluted butylene glycol produced no more than minimal skin irritation when tested under occlusion on the skin of rabbits for 24 hours or daily for 4 consecutive days. (JACT 4(5):223-248, 1985). However, Butylene glycol is considered to be non-irritating to human skin and mucous membranes. (Bingham et al., Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. NewYork, N.Y. (2001)., p. V7 45)

**Skin Sensitization:**

AFFIPORE (Cod.71700). Marzulli and Maibach Method: Human Repeated Insult Patch Test. Study in 50 volunteers, product tested at 15%. No irritation or sensitisation reaction was registered. Under the test conditions, the product AFFIPORE can be considered Non-irritating and No-sensitizing.

No sensitization was observed in a Repeated Insult Patch test (RIPT) in 200 volunteers and in extensive tests with butylene glycol-containing formulations at concentrations up to 16%. Several case reports have been published documenting allergic reactions in people who had used cosmetics containing butylene glycol. Considering the wide application of butylene glycol in cosmetics and food, the potential for skin sensitization is considered very weak. (ECHA Registration Dossier).

**Eye Irritation:**

It was realized a battery of tests to determine the ocular irritation potential of AFFIPORE (Cod.71700) at a concentration of 15%: Bovine Cornea Opacity and Permeability Test (BCOP), Irritation Index at 30 min = 1.0, Irritation Index 4 h = 15.7. Study of cytotoxicity in rabbit corneal fibroblasts (SIRC),Neutral Red Release Assay , IC50> 50%,% of mortality at dilution 50% < 20%. All these results show that the product can be considered Non-Irritant at Ocular level.

**Mutagenicity:**

AFFIPORE (Cod.71700): 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 0.041 and 5 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.

Diosmin is considered to have no mutagenic activity. (Alternative Medicine Review, 2004, 9(3):308-311)

Butylene glycol did not cause chromosomal aberrations in rat bone marrow cells in vivo. No evidence of carcinogenic activity was detected in a two-year dietary study in rats. (U.S. Environmental Protection Agency. Hazard Characterization Document, September 2010)

**Acute toxicity:**

In animal studies, a flavonoid mixture containing 90-percent diosmin and 10-percent hesperidin had an LD50 of more than 3g/kg. In addition, animal studies have shown the absence of acute, subacute, or chronic toxicity after repeated oral dosing for 13 and 26 weeks using a dose representing 35 times the recommended daily dose. The

standard dose of diosmin is 500 mg twice daily.(Alternative Medicine Review, 2004, 9(3):308-311)

The acute oral toxicity of Butylene Glycol in rats showed an LD50 of 22.8 g/kg. For acute inhalation toxicity, the LC50 was greater than 0.22 mg/L. (U.S. Environmental Protection Agency. Hazard Characterization Document, September 2010)

**Subchronic and chronic toxicity:**

In animal studies, a flavonoid mixture containing 90-percent diosmin and 10-percent hesperidin had an LD50 of more than 3g/kg. In addition, animal studies have shown the absence of acute, subacute, or chronic toxicity after repeated oral dosing for 13 and 26 weeks using a dose representing 35 times the recommended daily dose. The standard dose of diosmin is 500 mg twice daily.(Alternative Medicine Review, 2004, 9(3):308-311)

In a 13-week study in dogs, dietary administration of butylene glycol resulted in a NOAEL of 6000 mg/kg/day. In two-year studies with butylene glycol in the diet, a NOAEL of 7300 mg/kg/day was observed in rats (highest dose tested) and 589 mg/kg/day in dogs (highest dose tested). (U.S. Environmental Protection Agency. Hazard Characterization Document, September 2010)

**Reproductive effects:**

Barosma betulina, leaves. Pregnancy category B2: no increase in frequency of malformation or other harmful effects on the foetus from limited use in women. Animal studies are lacking. Although other references suggests that buchu is contraindicated in pregnancy, this would only be tha case fro buchu substituions (such as B. crenulata) that contain much higher levels of pulegone in their essential oil. Lactation category CC: Compatible with breastfeeding but use caution. (The Essential Guide to Herbal Safety, Simon Mills and Kerry Bone, Elsevier, First edition 2005, pp 295-297)

Diosmin is considered to have no embryo toxicity, nor any significant effect on reproductive function. Transplacental migration and passage into breast milk are minimal.(Alternative Medicine Review, 2004, 9(3):308-311)

Studies in rats with butylene glycol found a NOAEL of 7360 mg/kg/day for reproductive toxicity, 4120 mg/kg/day for developmental toxicity, and 706 mg/kg/day for maternal toxicity. (U.S. Environmental Protection Agency. Hazard Characterization Document, September 2010)

**Other data:**

AFFIPORE (Cod. 71700): In vitro phototoxicity study 3T3 NRU according to the EURL protocol ECVAM DB-ALM no. 78 and the Guideline OECD no. 432. According to the results obtained and under the experimental conditions adopted this product is classified as NON-PHOTOTOXIC.

In the in vivo efficacy study of AFFIPORE, 20 volunteers were treated for 28 days with 3% of the active. All the volunteers tolerated the product very well and there were no adverse effects.

A study was conducted in order to evaluate a considerable variety of natural sources and plants of diverse origin, to determine potential agents for the treatment of cancer. One of the products evaluated against neuroblastoma malignant cell line (N-2A) were the leaves of Barosma betulina. The results showed a slight to moderate effect, with an IC50 of 2923 mg/ml. (Phytother Res. 2009 March ; 23(3): 385:398)

Clinical study of topical application of a cream containing Buchu for the treatment of symptoms of pain and swelling from exercise-induced muscle damage. A group of 30 volunteers were divided into control group and group with Buchu. The treatment was performed prior to exercise and three times daily for 4 days after exercise. All volunteers tolerated the product and no adverse effects were reported. (MRC / UCT Research Unit of Exercise Science and Sports Medicine, Sports Science Institute of South Africa-)

Diosmin has been investigated in a number of animal models and human cancer cell lines, and has been found to be chemopreventive and antiproliferative.(Alternative Medicine Review, 2004, 9(3):308-311)

The efficacy and safety of a veno-active flavonoid fraction consisting of micronized diosmin (90%) and hesperidin (10%) have been studied in 100 patients with symptomatic capillary fragility in a double-blind, randomized, placebo-controlled trial. Treatment lasted 6 weeks and consisted of 2 daily tablets.The active was well tolerated and the results concluded that the treatment increases to a large extent the capillary resistance without significant side-effects. (Int Angiol. 1993 Mar;12(1):69-72)

## 4. ECOLOGICAL DATA

**Biodegradability:**

None test of biodegradability have been performed on this product. However we have been able to conclude that this product can be considered as easily biodegradable due to his composition and the raw material used, considering that the ingredients in this product are from vegetal origin.

Butylene Glycol: Biodegradation: 80.5% after 28 days (readily biodegradable).(U.S. Environmental Protection Agency. Hazard Characterization Document, September 2010)

**Aquatic Toxicity:**

Butylene Glycol: The 72-h EC50 value for aquatic plants was > 1070 mg/L (growth rate). (U.S. Environmental Protection Agency. Hazard Characterization Document, September 2010)

**Other data:**

No data available.

## 5. CONCLUSION

The European cosmetics legislation (Regulation (EC) No 1223/2009) establishes the need to assess the safety of cosmetic products, taking into account the toxicological profile of the ingredients. To do this, in the case of possible systemic effects, it is necessary to obtain the NOAEL (no observed adverse effects level) for the calculation of MoS (margin of safety). The absence of these considerations shall be duly justified.

The NOAEL value, or else other data used for the same purpose (LOAEL, LD50, etc.), can only be calculated experimentally from toxicological studies that require the use of animals. Since Provital does not perform any animal testing, it has established a system to ensure the safety of its products without the need of NOAEL and the subsequent calculation of MoS. This systematic, in the case of natural complex substances (NCS) has been endorsed by international organisms and renowned toxicologists.

The safety of this ingredient is then established based on the following information: known uses of the active in different fields (medicine, food, cosmetics, etc.), profile of the chemical compounds of the ingredient and bibliographic toxicological information available for the active and its components. The integration and study of all these data allows for a conclusion on the safety of the ingredient.

The components of this product have not registered adverse effects neither in its described uses or 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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