

2503000G – EXFO-OLIVE BODY

Version: 23 - 15/DEC/2020

1. PRODUCT IDENTIFICATION

Trade Name:	EXFO-OLIVE BODY
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):	Abrasives
Function of the Ingredient (UE Inventory):	Abrasive

2. PRODUCT COMPOSITION

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

[EU]		CAS	EINECS
Olea Europaea Seed Powder	100 %	8001-25-0	232-277-0

PCPC [CTFA]		CAS	EINECS
Olea Europaea (Olive) Seed Powder	100 %	---	---

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:

Composition of the olive stone: lignine (29-32 %), cellulose (27-28 %), hemicellulose (24-35 %) and salts (0.6-0.8 %). 52 % in weight of the stone is formed by carbohydrates. None of these compounds is considered to be dangerous for the health.

Classification according to Council of Europe (*):

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

Cytotoxicity:

No data available.

Skin Irritation:

No data available.

Skin Sensitization:

No data available.

Eye Irritation:

No data available.

Mutagenicity:

No data available.

Acute toxicity:

No data available.

Subchronic and chronic toxicity:

Olive stone is a fibre source potentially useful in animal food. It was performed an study with three experimental diets containing 0, 3 and 6% olive stone. 222 rabbits were fed during 45 days. At the end of the study, optimum health status were observed in all experimental groups. (Italian Journal of Animal Science, 2005 (Vol.4) (No. Supplement 3) 88-90)

Reproductive effects:

No data available.

Other data:

The use of olive stone as a physical superficial exfoliant, together with the size of its particles, prevents its cutaneous absorption and limits its bioavailability at cell level. For that reason no systemic toxicity effects were expected.

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 ingredient is 100% from vegetal origin.

Aquatic Toxicity:

No data available.

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 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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