

DECLARATION NOT NOVEL FOOD STATUS OF THE RAW MATERIAL “Mulberry Leaf Extract”

In accordance with Art. 4, point 1, of Regulation (EU) 2015/2283 on novel foods, it is considered that the ingredient marketed as “Mulberry Leaf Extract” does not fall within the definition of "novel food" as defined by Art. 3, point 2 of Regulation (EU) 2015/2283.

The mulberry leaf extract “Mulberry Leaf Extract” features a titer of 1-Deoxynojirimycin (1-DNJ) $\geq 5\%$. DNJ (1-Deoxynojirimycin) is a highly hydrophilic natural alkaloid present in mulberry leaves at a concentration that can reach up to 7 mg/g in the apical leaves (Marchetti et al, 2021).

Considering the maximum detected natural content of 0.7%, the application of a standard extraction and purification process (filtration and purification) with a drug/extract ratio (DER) of approximately 14:1 could allow the concentration of the active principle up to the 5% threshold. The production process (extraction, purification, concentrationfiltration, and drying) is of a traditional type and does not involve chemical modifications to the structure of 1-DNJ, but exclusively performs a normal concentration of it. Furthermore, in support of the above, it is reported that the raw material is obtained through hydroalcoholic extraction of *Morus alba*, a plant permitted in food supplements pursuant to Annex 1 of the Ministerial Decree of August 10, 2018, and subsequent amendments and additions, without any limitation, in addition to being listed in the “EU Novel Food status Catalogue” with the status: NOT Novel in Food Supplements.

Synonyms

Morus alba f. *alba*

Common Names

EN: White mulberry
BG: Бяла черница
DK: Hvid Morbær
NL: Moerbeï, Witte moerbeï
FI: Valkomulperi
FR: Mûrier blanc
SE: Vitt mullbär
DE: Weisse Maulbeere
GR: Ασπρι muria
IS: Hvítt mórber
IT: Gelso bianco
NO: Kvitmorbær, hvitmorbær
PT: Amoreira branca
PL: Morwa biała
ES: Mora

Description

The entry concerns the fruit, young leaves, stem and rhizome of *Morus alba* L.

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STATUS

• Fruit



NOT NOVEL IN FOOD - According to the information available to the Member States' competent authorities, this product was used for human consumption to a significant degree within the Union before 15 May 1997. Thus, it is not considered to be 'novel' according to the provisions of the Novel Food Regulation (EU) 2015/2283 and its access to the market is not subject to the pre-market authorisation in accordance with Regulation (EU) 2015/2283.

However, other legislation may restrict the placing on the market of this product as a food in the EU or in some Member States. Therefore, it is recommended to check with the **competent authority(ies)** of the Member State(s).

• Young leaves, stem and rhizome (root bark)



NOT NOVEL IN FOOD SUPPLEMENTS - According to the information available to Member States' competent authorities, this product was used in food supplements in the EU before 15 May 1997. Therefore, its use in food supplements is not considered to be novel and is not subject to the pre-market authorisation in accordance with Regulation (EU) 2015/2283.

Any other food uses of this product, other than as, or in, food supplements, might be considered to be novel and consequently might need to be authorised pursuant to the requirements of the Novel Food Regulation (EU) 2015/2283 before they can be placed as food on the EU market.

In addition, other legislation may restrict the placing on the market of this product as a food in the EU or in some Member States. Therefore, it is recommended to check with the **competent authority(ies)** of the Member State(s).

Bibliography:

- Marchetti, L.; Saviane, A.; Montà, A.d.; Paglia, G.; Pellati, F.; Benvenuti, S.; Bertelli, D.; Cappelozza, S. Determination of 1-Deoxynojirimycin (1-DNJ) in Leaves of Italian or Italy-Adapted Cultivars of Mulberry (*Morus* sp.pl.) by HPLC-MS. *Plants* 2021, 10, 1553.
<https://doi.org/10.3390/plants10081553>

For and on behalf of
Ingredients4u Limited

Chunyan Wu
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Authorized Signature(s)

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