



This statement is valid until 31.01.2025

Product Information Sheet for Stearina Vegetale B1804 MB

Thank you for your interest in our products. This letter is in response to your inquiry. A.Gallo can state on:

Information on feedstock

- Vegetable origin
- BSE/TSE status
- Vegan status
- GMO status
- Allergens acc. to Cosmetics Regulation, Food Regulation and Alba List
- Jatropha

Information on REACH

- REACH status according EC/1907/2006
- Absence of CMR-substances (Category 1A, 1B or 2) acc. EC/1272/2008 (amended on 11th March 2021 by EU/2021/849)
- Absence of SVHC-substances, substances of the authorization list (annex XIV) and substances of the restriction list (annex XVII) acc. EC/1907/2006

Information on Contaminants

- Various substances
- Substances acc. to Cosmetics Regulation EC/1223/2009 (incl. Annex II, III, IV, V, VI)
- Heavy Metal status
- Microbiological status

Miscellaneous Information

- NAGOYA protocol and Regulation EU/511/2014
- Status acc. to the definitions of ISO 16128-1 and calculation of natural origin index acc. ISO 16128-2
- Ionization or Irradiation
- Absence of Casserite (Tin), Columbite-Tantalite (Tantal), Gold and Wolframite (Tungsten)
- Absence of Nanomaterials
- Non Animal testing status

Information on feedstock

Vegetable origin of Stearina Vegetale B1804 MB

A.Gallo can state that **Stearina Vegetale B1804 MB** is exclusively processed from vegetable raw materials. Subsequent statements are based on this general principle of A.Gallo.

BSE/TSE status of Stearina Vegetale B1804 MB

Due to the vegetable status of **Stearina Vegetale B1804 MB** any BSE/TSE risk is excluded. As described above, this product does neither contain nor comes into contact with human or animal derived materials during manufacturing, by starting materials / reagents or intermediates.

Vegan status of Stearina Vegetale B1804 MB

Based on the above given information and due to the fact that no animal or human derived intermediates and processing aids are deployed during the processing of **Stearina Vegetale B1804 MB**, this product can be consequently designated as vegan.

Furthermore **Stearina Vegetale B1804 MB** is certified as kosher and halal.

GMO status of Stearina Vegetale B1804 MB

The raw materials used in the manufacture of **Stearina Vegetale B1804 MB** are confirmed as not containing, consisting of or produced from Genetically Modified Organisms. **Stearina Vegetale B1804 MB** can be declared as GMO free (ref. GMO labelling criteria appearing in Regulation EC/1830/2003).

Allergens acc. to Cosmetics Regulation, Food Regulation and Alba List in Stearina Vegetale B1804 MB

The vegetable raw materials used are not cited in:

- the Cosmetics Regulation EC/1223/2009, including all amendments up to 26.07.2023 by EU/2023/1545,
- the Food Regulation EU/1169/2011, Annex II, including all amendments to EU/2015/2283,
- the Alba list.

Therefore, to the best of our knowledge Allergens in accordance to the above-mentioned standards are not expected to be present in **Stearina Vegetale B1804 MB**. Hence, no standard analysis is carried out.

Jatropha in Stearina Vegetale B1804 MB

A.Gallo can confirm that Jatropha is not applied as raw material for the production of **Stearina Vegetale B1804 MB**.

Information on REACH

REACH status according EC/1907/2006 of Stearina Vegetale B1804 MB

A.Gallo can state, that the REACH status of the product **Stearina Vegetale B1804 MB** is provided in chapter 1 of the specific MSDS of the product.

Absence of CMR-substances (Category 1A, 1B or 2) acc. EC/1272/2008 (amended on 11th March 2021 by EU/2021/849) in Stearina Vegetale B1804 MB

A.Gallo can state that our product **Stearina Vegetale B1804 MB** is neither a CMR- substance according to the provisions laid down in Regulation EC/1272/2008 annex I, part 3 nor listed in annex VI, part 3 of the beforementioned regulation. In addition, it has not to be expected that CMR-substances are unintentional contaminants of our products.

Therefore, unless laboratory tests are conducted that conclusively prove otherwise, to the best of our knowledge, CMR-substances are unlikely to be present in appreciable amounts in **Stearina Vegetale B1804 MB**. Hence no standard analysis is carried out.

Absence of SVHC-substances, substances of the authorization list (annex XIV) and substances of the restriction list (annex XVII) acc. EC/1907/2006 in Stearina Vegetale B1804 MB

A.Gallo can state that our product **Stearina Vegetale B1804 MB** is neither a SVHC nor contains components originating from SVHC as cited on the ECHA candidate list update 23.01.2024. It can be stated too, that **Stearina Vegetale B1804 MB** is neither listed on nor contains this product substances from the ECHA authorization list, updated on EU 2023/2482 from 13.11.2023 or from the ECHA restriction list, updated on EU 2023/2055 from 25.09.2023 respectively.

Therefore, unless laboratory tests are conducted that conclusively prove otherwise, to the best of our knowledge, SVHC-substances, substances of the restriction list and substances of the authorization list are unlikely to be present in appreciable amounts in **Stearina Vegetale B1804 MB**. Hence, no standard analysis is carried out

Information on Contaminants

Various substances in Stearina Vegetale B1804 MB

As a supplier of a raw material, A.Gallo is not aware about specific intended purposes of our valued customer at all times. However, Stearina Vegetale B1804 MB is manufactured as technical grade to the highest standards possible.

If an intended purpose of our valued customer requires specific regulatory requirements, please review those requirements depending from your application. Nevertheless, A.Gallo can rule out numerous substances, since they are not used during manufacturing.

This includes:

- Melamine
- Bisphenol A
- Latex
- Gluten
- Solvents, incl. Methanol / Ethanol
- Substances as listed in California Proposition 65
- Lactose
- Microplastic
- Preservatives / Additives
- Phthalates
- Asbestos
- Ethylenoxide / 2-Chlorethanol
- Nitrosamine

A.Gallo can confirm that the above-mentioned substances are not added intentionally during the processing of **Stearina Vegetale B1804 MB**. In addition, it has not to be expected that these substances are unintentional contaminants of the product since they are not processed on site. Therefore, unless laboratory tests are conducted that conclusively prove otherwise, to the best of our knowledge, the above-mentioned substances are unlikely to be present in appreciable amounts in **Stearina Vegetale B1804 MB**. Hence no standard analysis is carried out.

Substances acc. to Cosmetics Regulation EC/1223/2009 (incl. Annex II, III, IV, V, VI) in Stearina Vegetale B1804 MB

A.Gallo confirms that the prohibited substances listed in Annex II (last amended on 19.07.2023 by EU/2023/1490) as well as substances listed in Annex III (last amended on 26.07.2023 by EU/2023/1545), which are subject to restrictions and conditions, this includes allergenic fragrances as well, are neither intentionally added nor expected to be added.

Annex IV on coloring agents subjected to restrictions and conditions (last amended on 26.05.2021 by EU/2021/850), Annex V on preservative substances subjected to restrictions and conditions (last amended on 15.09.2022 by EU/2022/1531) and Annex VI on UV filters allowed in cosmetic products (last amended on 10.11.2022 by EU/2022/2195) are not applicable for **Stearina Vegetale B1804 MB**. **Stearina Vegetale B1804 MB** is neither a coloring agent, preservative, UV filter nor are such substances added intentionally.

Therefore, unless laboratory tests are conducted that conclusively prove otherwise, to the best of our knowledge, substances regulated by EC/1223/2009 are unlikely to be present in appreciable amounts in **Stearina Vegetale B1804 MB**. Hence no standard analysis is carried out.

Heavy Metal status of Stearina Vegetale B1804 MB

A.Gallo can state that **Stearina Vegetale B1804 MB** is undergoing a selective purification process when being evaporated under vacuum during distillation. Even if Heavy metal catalysts might be used for manufacturing of **Stearina Vegetale B1804 MB**, metal residues are unlikely to be present as Heavy metal traces will remain in the residue.

Therefore A.Gallo can confirm that Heavy Metals (summed up: Cd, Cu, Fe, Ni, Pb, Zn, As, Hg, Sn, Cr, Mn) in Stearina Vegetale B1804 MB will be situated <10 mg/kg . Analyses on Heavy Metals is performed on statistical bases.

Microbiological status of Stearina Vegetale B1804 MB

A.Gallo can state that a microbiological contamination is assessed as very unlikely. This assessment bases on the fact, that the processing conditions (high temperature >200°C, closed plant) prevent from microbiological contamination. Furthermore, **Stearina Vegetale B1804 MB** has a very low water activity. Therefore, a microbiological risk should not be expected and hence no standard analysis is carried out.

Nevertheless, the product is not filled under sterile conditions, neither for bulk deliveries nor during packaging in Drums/IBCs/Bags or Big Bags and therefore the product cannot be considered as sterile.

Miscellaneous Information

NAGOYA protocol and Regulation EU/511/2014

With reference to article 2 of the above mentioned European regulation, the Nagoya protocol applies only to genetic resources and traditional knowledge associated with genetic resources. Additionally, Article 3 defines genetic resources as genetic material of actual or potential value, whereby genetic material means any material of any source with functional heredities.

A.Gallo uses raw materials for the further production of Oleochemicals and not for the exploitation of functional heredities.

This leads to the conclusion that, to the best of our knowledge, **Stearina Vegetale B1804 MB** is not manufactured under the conditions of Regulation EU/511/2014. Therefore the NAGOYA protocol is considered by A.Gallo as not to be applicable.

Status acc. to the definitions of ISO 16128-1 and calculation of natural origin index acc. ISO 16128-2 for Stearina Vegetale B1804 MB

A.Gallo can state that **Stearina Vegetale B1804 MB** derives exclusively from vegetable oils. These oils are mainly prepared by physical processes (e.g. seed crushing, grinding) which are covered by ISO 16128-1 in chapter 2.1. For the manufacturing of vegetable oils, extraction steps with solvents should be considered additionally. Such extractions with “process solvents” acc. annex A, table A.2 of ISO 16128-1 seems to be permitted as well. Therefore, the deployed vegetable oils for the manufacturing **Stearina Vegetale B1804 MB** can be designated as “natural”.

These “natural” oils are splitted by Hydrolysis (acc. Table B.1 ISO 16128-1), leading to a permitted “chemical modification” acc. Chapter 3.1 of ISO 16128-1. The fatty acid phase of this Hydrolysis becomes concentrated by distillation and, if necessary, hydrogenated. Distillation is indeed a physical process according to the requirements of a natural product, but the chemical modifications - hydrolysis and, if necessary, hydrogenation - are the determining steps, leading to a “natural derived” product.

Finally, more than 50% of a “derived natural product” must originate from ingredients of “natural origin”. As **Stearina Vegetale B1804 MB** derives exclusively from Fatty Acids obtained by the procedure described above, this requirement is fulfilled as well.

Summarizing the interpretation of ISO 16128-1 given above, **Stearina Vegetale B1804 MB** is a “derived natural” product, which is produced from “natural” raw materials greater than 50% with permitted reactions acc. ISO 16128-1.

As no further constituents are added to **Stearina Vegetale B1804 MB**, the natural origin index can be considered as 1 in accordance to ISO16128-2.

Ionization or Irradiation of Stearina Vegetale B1804 MB

A.Gallo can confirm that neither ionization nor irradiation as described within European Directives 1999/2/EC and 1999/3/EC takes place during processing, packaging and transport of **Stearina Vegetale B1804 MB**.

Absence of Casserite (Tin), Columbite-Tantalite (Tantal), Gold and Wolframite (Tungsten) in Stearina Vegetale B1804 MB

A.Gallo can confirm that the substances mentioned above are not added intentionally during the processing of **Stearina Vegetale B1804 MB**. In addition, it has not to be expected that these substances are unintentional contaminants of this product. Furthermore it can be stated, that none of the above-mentioned minerals are used for any product of A.Gallo.

Therefore, unless laboratory tests are conducted that conclusively prove otherwise, to the best of our knowledge, conflict minerals are unlikely to be present in appreciable amounts in **Stearina Vegetale**

B1804 MB. Hence, no standard analysis is carried out.

Absence of Nanomaterials in Stearina Vegetale B1804 MB

In compliance with the definition of Nanomaterials, laid down within Commission Recommendation 2011/696/EU and Regulation EU/2017/745, we would like to confirm that **Stearina Vegetale B1804 MB** is not

affected by this classification. The above mentioned product neither consists of Nanomaterial nor are Nanomaterials intentionally added during processing, packaging and transport.

Non Animal testing status of Stearina Vegetale B1804 MB

A.Gallo can confirm that no animal testing, except it is required by law, has been performed on demand of A.Gallo with regard to **Stearina Vegetale B1804 MB**.

Particularly no animal testing took place for cosmetic purpose. Be aware that, due to Commission Implementing Regulation EU/2020/1435, animal testing might be possible in order to comply with Regulation

EC/1907/2006 (REACH).

Signed by Quality Management A.Gallo (Certificate is system generated and does not require signature)