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PRODUCT REGULATORY DATASHEET

Section 1 - Product Information

Carnauba Wax NF, Carnauba Wax,
Carnauba Wax Powder, NF,
Carnauba Wax Extra Fine Powder, NF
Carnauba Wax Powder/Extra Fine Powder NF/EP

Scope: To provide complete product portfolio to the users including regulatory and manufacturing information.

Carnauba Wax is a natural wax obtained from the leaves of the palm tree known as *Copernicia cerifera*. This palm flourishes in the northeastern regions of Brazil.

Carnauba Wax is offered in flakes, lumps, and powder. It is compatible with most animal, vegetable and mineral waxes and a large variety of natural and synthetic resins.

Section 2 - Manufacturing, Packaging and Release Site Information

The producer's manufacturing facility is located in the USA. All of Carnauba Wax is produced at this site. The product can also be obtained through our network of distributors throughout the world.

The producer's Quality System is modeled after ISO-9001 and they have incorporated practices from IPEC Good Manufacturing Practices Guidelines for Bulk Excipient Manufactures.

Carnauba wax production is internally controlled through the execution of a HACCP program.

The producer does not employ irradiation or ethylene oxide sterilization in any part of our facility nor do we purchase ETO sterilized ingredients.

Every finished product is designated a unique batch number sequentially assigned with the suffix "/XX" indicating the year in which it was manufactured. The unique batch number combined with batch sheets allows for full traceability of each raw ingredient.

Every package is minimally labeled with the batch number, product code, Gross/Tare/Net weights, date of manufacture and date of retest.

Section 3 - Physical/Chemical Information

CAS Number: 8015-86-9
EINECS Number: 232-399-4
INCI Name: *Copernicia cerifera (carnauba) wax*.
Country of Origin: USA
Composition: 100%

Section 4 - Regulatory Information

The producer fully tests the Carnauba Waxes to the NF monograph.

If tested, Carnauba Wax, NF will conform to the EP, BP, JP, and ChP monographs.

Carnauba wax is listed in the European Food Safety Authority as code E 903.

Since 1904, the creation date of the company, The producer has never performed and does not intend to perform any animal testing for Cosmetic purposes or other purposes.

Carnauba Wax is FDA approved for end use under regulations 21 CFR 184.1978 and 175.320 and is CTFA listed.

Carnauba Wax is **GRAS** listed.

Carnauba Waxes do not contain any preservatives.

worldwide Registration Status: Carnauba Wax has no known restrictions of use.

BSE/TSE Information: Carnauba Wax is BSE/TSE free.

Allergens/Hypersensitivities: Carnauba Waxes do not contain known fragrance or food allergens, including gluten.

GMO Information: The producer's products are GMO free

Residual Solvents Information: The producer manufactures Carnauba Wax without the use of solvents. The producer tests Carnauba Wax according to the USP <467> General Chapter to insure compliance with Residual Solvents and to date no solvents has been detected at or above the limits.

VOC: According to the VOC definition of the EC Directive 1999/13/EC, Carnauba wax does not contain any VOC.

Kosher status: Kosher Carnauba Wax is certified by Kosher Technical Korisultants to be Kosher.

Elemental Impurities: Those metals currently listed in the draft USP <232>, ICH, and EMEA are not likely to be present. We do not currently test for any metals due to the unlikelyhood of their presence.

Proposition 65: Carnauba Waxes do not contain any chemicals listed.

Nutritional Content: Waxes, in general, are indigestible and therefore have no nutritional value.

Microbial Content: Waxes, in general, do not support microbial growth. The producer does not perform microbial testing. However, based on the nature of the wax and our manufacturing process, the producer can reasonably state that microbes should not be present in our waxes.

Impurities: Based on the knowledge of the origin of the wax and the manufacturing process, the producer do not expect to find the following in our carnauba wax:

Corn	Sulfates
Saccharin	Parabens
Hormones	Synthetic Fragrances
Antibiotics	Dyes
Antigens	Petrochemicals
Hyaluronic acid and its sodium salts	Triclosan
Polycyclic Aromatic Hydrocarbons (PAH)	GMO
Phthalates	Formaldehyde
Artificial Color	Surfactants
BHT/BHA	EDTA

The producer does not test for any of the above impurities.

Pesticides: Carnauba Wax is harvested in areas where no pesticides are used. The producer can reasonable state that our Carnauba waxes are pesticide free. The producer annually tests each supplier to insure conformance.

Section 5 -Miscellaneous Product Information

Carnauba Waxes have a retest date of 3 years.

Carnauba Wax is a naturally occurring material and can be considered biodegradable.

Carnauba Wax Harmonized Tariff Schedule (HTS#) is 1521.10.0040.

Section 6 Revision history

Issue Date: 07/24/13

Revision 1; 09/28/11

Revision 2: 07/24/13

Revision 3: 01/2016 Added additional impurities. Added line for date after signature

Revision 4: 11/01/18; added additional impurities, Changed the header for LL