Please note that this material does not legally require an SDS according to Article 31 (1) of REACH (as amended by Articles 58(2)(a) and 59(2)(a) of CLP)

- Content: silk 81-94%, coating 5 -18%, dye <1%
- The origin of the raw silk supplied is China and the species is stated on the certificate of conformity as Bombyx Mori L along with the grade being 4A or above. The polymer is a natural protein from the silk worm.
- The raw silk material is inspected to International Silk Association Standards and graded at source to exceed the requirements of Chinese National Standard GB/T 1797-2008.
- Logwood dye (oxidized logwood extract) CI75290. EC 270-977-1, CAS 90294-88-5 conforms to FDA 21 CFR 73.1410
- Wax coating purified beeswax from Apis Meliafera CAS 8006-40-4 conforms to the European Pharmacopeia.
- Animal additives are not contained within or used during the manufacturing process either as an additive, expedient, adjuvant, or as a simple utility or technical tool such as performing as a lubricant.
- Silk product is Latex free, Paraben free, TSE free, mint free, does not contain Polyvinyl chloride (PVC), p-tert-Butylphenol Formaldehyde Resin (PTBP-F-R), Bisphenol A or phthalates: Benzyl butyl phthalate (BBP) Bis(2-ethyl(hexyl)phthalate (DEHP) Dibutyl phthalate (DBP) Diisobutyl phthalate (DIBP) in their basis material or coating composition
- The material complies with: California Proposition 65 (PROP65), R.O.H.S. WEEE and REACh 2006 SVHC latest revision at less than 0.1%.

- **COMPONENT SDS**
  - **SILK**

TESTEX AG, SWISS TEXTILE TESTING INSTITUTE
GOTTHARDSTRASSE 61
8002 ZURICH, SWITZERLAND

OEKO-TEX®
INSPIRING CONFIDENCE

CERTIFICATE

The company

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
SH005 121963 TESTEX
Tested for harmful substances
www.oeko-tex.com/standard100

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **SH005 190368.1**

for the following articles:

Yarns made of 100% silk, raw white

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Annex 6, **product class II** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Annex 6 for products with direct contact to skin.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate SH005 121963 is valid until 15.10.2022

Zurich, 20.09.2021

Matz Bachmann
Managing Director

Faisal Rizal
Ecology Team Leader

OEKO-TEX® Association | Genferstrasse 23 | CH-8002 Zurich

- **BEESWAX COATING**

This substance does not require legally SDS according to Article 31 of the REACH Regulation (1907/2006).
This document is intended to inform the downstream user of the status of this substance under REACH and CLP, some of its intrinsic properties and communicate a guidance of safety use as mentioned in Article 32 of Regulation REACH.
Consequently, it cannot be the object of non-compliance under Regulation (EC) 453/2010 and it cannot be subject to the same requirements.

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name	:	CERABEIL WHITE DAB
CAS	:	8012-89-3 or 8006-40-4
EC	:	232-383-7
REACH Status	:	Exempted according Annexe V

- **DYE**

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**
· **Trade name:** HEMATINE HCKS21
· **EC number:**
290-977-1
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use**
SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
SU5 Manufacture of textiles, leather, fur
SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
· **Product category**
PC23 Leather tanning, dye, finishing, impregnation and care products
PC34 Textile dyes, finishing and impregnating products; including bleaches and other processing aids
· **Process category**
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
· **Environmental release category**
ERC5 Industrial use resulting in inclusion into or onto a matrix
ERC2 Formulation of preparations
· **Application of the substance / the preparation** Dyestuff/Colouring agent

2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified according to the CLP regulation.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
· **Information concerning particular hazards for human and environment:**
No hazards to be particularly mentioned. Please note the information of this Material Safety Data Sheet.
· **Classification system:**
The classification is in line with current EC lists. It is extended by information from technical literature and company information.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Substances**
· **CAS No. Description**
Oxidized Logwood extract
· **Identification number(s)**
· **EC number:** 290-977-1

[Code of Federal Regulations]
[Title 21, Volume 1]
[Revised as of April 1, 2019]
[CITE: 21CFR73.1410]
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL
PART 73 -- LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION
Subpart B--Drugs
Sec. 73.1410 Logwood extract.

(a) Identity. The color additive logwood extract is a reddish brown-to-black solid material extracted from the heartwood of the leguminous tree Haematoxylon campechianum. The active colorant substance is principally hematein. The latent coloring material is the unoxidized or leuco form of hematein called hematoxylin. The leuco form is oxidized by air.

(b) Specifications. Logwood extract shall conform to the following specifications and shall be free from impurities other than those named to the extent that such imnurities may be avoided by good manufacturing practice:

Volatile matter (at 110 deg. C), not more than 15 percent.

Sulfated ash, not more than 20 percent.

Hematein, not less than 5 percent and not more than 20 percent.

Lead (as Pb), not more than 70 parts per million.

Arsenic (as As), not more than 4 parts per million.

Mercury (as Hg), not more than 3 parts per million.

(c) Use and restrictions. Logwood extract may be safely used to color nylon 66 (the copolymer of hexamethylenediamine and adipic acid), nylon 6 (the polymer of e -caprolactam), or silk non-absorable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1.0 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) Labeling. The label of the color additive shall conform to the requirements of 70.25 of this chapter.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 52393, Sept. 30, 1977; 43 FR 1490, Jan. 10, 1978]

NOTE: supplier information is the most current at the time of issue of this document