



Publicly Certified and Authorized Expert for
Toxicology of Cosmetics and Consumer Goods
Attested by the Chamber of Commerce (IHK) „Mittlerer
Niederrhein“

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Certificate

Legal Compliance and Safety Assessment

of

Seaweed Fibre “VY9005350TP” for Use in Tampons as Absorbent Core (or part of it as a mix with cotton or viscose)

Herewith we do certify, that **seaweed fibre “VY9005350TP”** from the producer/supplier:

Vyld GmbH, Richardstraße 85/86, 12043 Berlin
Contact: Ines Schiller: ines@vyldness.de

intended to be used as:

absorbent core (or part of it) of feminine hygiene products, i.e. tampons, is in legal compliance with relevant toxicological safety obligations; it can safely be used for up to 100 % in the absorbent core.

These fibres fulfil mandatory legal provisions of Directive 2001/95/EC of the European Parliament and of the Council of 03/12/2001 on general product safety (GPSD: available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095>), the forthcoming Regulation (EU) 2023/988 of the European Parliament and of the Council of 10/05/2023 on general product safety (GPSR; available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0988>), and hence the German Code for Food, Consumer Goods and Feed (LFGB: “*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*”; in German available at: <https://www.gesetze-im-internet.de/lfgb/>).

A legal compliance and toxicological safety assessment of this seaweed-based fibre for the production of absorbent cores of tampons has been carried out (as has been documented in the respective report, dated 12/09/2024).

This legal compliance and toxicological safety assessment takes into account key steps for a systematic approach, which includes a hazard assessment of the compositional substance Calcium alginate fibre including its unavoidable residues and impurities, which may potentially be released from the tampon core during its use, a human exposure and safety assessment by means of a risk evaluation.

Proven by biological/toxicological testing for *in vitro* cytotoxicity, and *in vivo* skin sensitization, this material does not pose a risk for adverse health effects by compositional, residual and potentially released substances and degradation products.

It is devoid of substances at toxicologically relevant amounts which are carcinogenic, mutagenic or toxic to reproduction (CMR), skin sensitizing and irritative/corrosive to skin/vaginal mucosa, or of substances having endocrine disrupting (ED) properties.

Due to the toxicological innocuousness of the Calcium alginate fibre, no adverse health effects are to be expected when this material is used for the production of the absorbent core (or part of it) of the menstrual product tampon.

Seaweed is known to absorb (heavy) metals from its surrounding environment. Therefore, (heavy) metal contents were analytically determined in the dry product. However, since seaweed has a high affinity to (heavy) metals and thus rather binds than releases them, the concentrations of (heavy) metals in extracts of synthetic menses have been additionally determined to better reflect the foreseeable physiological conditions of tampon usage.

Levels of all 11 (heavy) metals, i.e. Antimony, Arsenic, Barium, Lead, Cadmium, Chromium, Cobalt, Copper, Mercury, Nickel, and Selenium, analytically determined were (far) below their PDEs (Permitted Daily Exposure), which already define safe levels for lifetime daily exposure of humans. This includes levels relevant for flare-up skin reactions for Nickel.

Thus, any health impairment by (heavy) metals from the use of the seaweed-based Calcium alginate fibre is not to be expected.

In addition, the amount of the preservative Formaldehyde was analytically determined, which was also below the conservatively derived level for elicitation of skin sensitization.

The material Calcium alginate fibre is devoid of any critical contamination with microorganisms which could lead to a health hazard for the user of tampons as tested in accordance with the European Pharmacopoeia.

Additionally, this material does not interact with the vaginal microbiome and does not influence growth behaviour of the pathogen *Staphylococcus aureus*; there exists an indication that it may reduce production of Toxic Shock Syndrome Toxin (TSST-1), actually, no enhancement could be verified.

Thus, the material seaweed fibre “VY9005350TP” does fulfil the respective mandatory legal and recommended normative requirements as have been defined for consumer products according to legal provisions of Directive 2001/95/EC and also the forthcoming Regulation (EU) 2023/988 on general product safety applying a biological/toxicological safety assessment as is also mandated by the provisions of § 30 and 31 of the (German) Food, Consumer Goods and Animal Feed Code (LFGB) in that consumers should not be exposed to any toxicologically critical substances.

In conclusion, the material seaweed fibre “VY9005350TP” is safe for its intended use for up to 100 % as absorbent core of tampons.



2024-10-04

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2024-10-04

Natalia Jansen- Bouriatchenko
Regulatory Affairs Manager
Publicly Certified and Authorized Expert for
Toxicological Risk Assessments of Cosmetics
and Consumer Goods

Attachment to

**Certificate: Legal Compliance and Safety Assessment of Seaweed Fibre
“VY9005350TP” for Use in Tampons as Absorbent Core (or part of it as a mix with
cotton or viscose), dated 04/10/2024**



reads:

Dr. Joachim Haselbach
Toxicology of Cosmetics and Consumer Goods
Publicly Certified and Authorized by Chamber of Industry and Commerce



reads:

Natalia Bouriatchenko
Toxicological Risk Assessment of Cosmetics and Consumer Goods
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