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English Version

## Algae and algae products - Specifications for pharmaceutical sector applications

Algues et produits d'algues - Spécifications pour les  
applications dans le secteur pharmaceutique

Spezifikationen für Anwendungen im Nicht-  
Lebensmittel-/Futtermittelsektor

This Technical Report was approved by CEN on 4 January 2021. It has been drawn up by the Technical Committee CEN/TC 454.

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## **European foreword**

This document (CEN/TR 17612:2021) has been prepared by Technical Committee CEN/TC 454 “Algae and algae products”, the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

The European committee for Standardization (CEN) was requested by the European Commission (EC) to draft European standards or European standardization deliverables to support the implementation of Article 3 or Directive 2009/28/EC for algae and algae products or intermediates. The request presented as Mandate M/547, also contributes to the Communication on “Innovating for Sustainable Growth: A Bio economy for Europe”.

The former working group CEN Technical Board Working Group 218 “Algae” was created in 2016 to develop a work programme as part of the Mandate. The technical committee CEN/TC 454 “Algae and algae products” was established to carry out the work program the secretariat of which is held by NEN. CEN/TC 454 set up a number of topic specific working Groups listed below to develop standards for algae and algae products.

This document has been prepared by Working Group 5 “Specifications for the pharmaceutical applications sector” with the support of UNI as the secretariat, in close collaboration with the other CEN/TC 454 working groups:

CEN/TC 454/WG 1 “Terminology”;

CEN/TC 454/WG 2 “Identification”;

CEN/TC 454/WG 3 “Productivity”;

CEN/TC 454/WG 4 “Specifications for food/feed sectors applications”;

CEN/TC 454/WG 6 “Product test methods”.

Algae-based products and intermediates, in this TR referred to as ‘products’, are defined as whole biomass, extracts or derivatives from algae, including a.o. algae oil and algal meal.

This document will allow the stakeholders to have access to a clear point of reference on the use of algae in pharmaceuticals.

Pharmacy had standards which date back to ancient Egypt; through the first pharmacopoeias which were the Arab one, the Totum continens (Elhavi) of ar-Razi, and that of the Salerno medical school.

Then national Pharmacopoeias developed in Europe in the Eighteenth Century.

Today pharmaceutical industry has the European Pharmacopoeia (EP) [3], with legal status according medicinal regulatory framework (Annex A), being harmonized with American (USP) [4] and Japanese (JP) [5] through ICH [6].

## Introduction

The interest in algae and algae-based products or intermediates as a renewable and sustainable source of carbohydrates, proteins, lipids and pigments has increased significantly in Europe.

The purpose of this document prepared by WG 5 is to provide an overview on how quality indicating parameters for algae and algae-based products and intermediates relevant for pharmaceutical applications can be handled and to identify the need for any future standard developments for pharmaceutical applications. Algae are highly available and used in many countries as fertiliser, biostimulant, animal feed, medicine, cosmetic and food ingredients, and have different compounds depending on species.

## 1 Scope

This document gives an overview of recommendations on product specifications, and other relevant information, for algae and algae products for pharmaceutical applications.

This document does not apply to food and feed applications.

This document does not provide instructions on handling of technical requirements in existing legislations.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 16751, *Bio-based products - Sustainability criteria*

EN 16760, *Bio-based products - Life Cycle Assessment*

EN 16848, *Bio-based products - Requirements for Business to Business communication of characteristics using a Data Sheet*

EN 16935, *Bio-based products - Requirements for Business-to-Consumer communication and claims*

EN 17399, *Algae and algae products - Terms and definitions*

EN 17477<sup>1</sup>, *Algae and algae products - Identification of the biomass of microalgae, macroalgae, cyanobacteria and Labyrinthulomycetes - Detection and identification with morphological and/or molecular methods*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 17399 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

### 3.1 algae and algae products

functional group of organisms consisting of microalgae, macroalgae, cyanobacteria, labyrinthulomycetes and products derived thereof

### 3.2 Raw Material Specification RMS

several pages technical dossier about the product, usually prepared by manufacturer, directed to provide all product approval information to the customer and usually attached to commercial contract

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<sup>1</sup> Under preparation. Stage at the time of publication: prEN 17477.