

**FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY
JECFA**

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

Name of Substance(s):	INS 445iii, GLYCEROL ESTER OF WOOD ROSIN (GEWR)
Question(s) to be answered by JECFA <i>(Provide a brief justification of the request in case of re-evaluations)</i>	Request for a revision of specifications for INS 445(iii) GEWR The purpose is to revise the applicable specifications which restrict the source material (aged pinus stump(s)) to only two pinus species (<i>Pinus palustris</i> and <i>Pinus elliottii</i>). Such restriction was not laid down in the definition of the specifications for GEWR prior to 2011 and it could be considered as trade restrictive taking into account that there are over 175 species of pine trees worldwide and that some others than <i>Pinus palustris</i> and <i>Pinus elliottii</i> are also suitable for rosin production (e.g. <i>Pinus halepensis</i>). The intention is to demonstrate a chemical equivalence between GEWR produced from <i>Pinus palustris</i> and <i>Pinus elliottii</i> and from other pinus species (Resinas 8WR).

1. Proposal for inclusion submitted by:

Hellenic Food Authority EFET

L. Kifisias 124 & Iatridou 2

115 26 Athens, Greece

2. Name of substance; trade name(s); chemical name(s):

Substance : Glycerol Ester of Wood Rosin

Trade name : Resinas 8WR;

Chemical Name : Rosin acids; esters with glycerol

CAS 8050-30-4

3. Name and address of basic producer: (wood rosin feedstock producer)

Megara Resins- Anastasios Fanis S.A.

38th km New National Road Athens-Corinth

191 00 Megara, Greece

Name and address of basic manufacturer: (“glycerol esters of wood rosins”-Resinas 8WR)

Resinas Sinteticas León Tolstoi 18, suite 101, Col. Anzúres, Mexico City.

4. Has the manufacturer made a commitment to provide data?

Yes, Resinas Sinteticas (T&R Chemicals) commits to provide data to support its request.

5. Identification of the manufacturer that will be providing data (Please indicate contact person):

Resinas Sinteticas León Tolstoi 18, suite 101, Col. Anzúres, Mexico City.

T&R Chemicals, Inc. 700 Celum Road Clint, Texas 79836 USA

6. Justification for use:

The request relates to the revision of specifications which does not have any impact on the justification for the use of INS 445(iii) as currently recognized. INS 445(iii) acts as an emulsifier and a stabilizer, e.g. by (i) increasing the density of non-alcoholic flavored beverages so as to maintain uniform suspension in the end products; (ii) adding desirable degree of cloudiness to finished beverages, and (iii) improving stability of finished non-alcoholic beverages.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

The use of INS 445(iii) is in the GSFA recognized in the following categories:

04.1.1.2 Surface-treated fresh fruit at 110 mg/kg

04.2.1.2 Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds at 110 mg/kg

14.1.4 Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks at 150 mg/kg

The request for the revision of specifications does not have any impact on the currently permitted uses.

8. Is the substance currently used in food that is legally traded in more than one country? or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

YES

Glycerol esters of wood rosins is a food additive authorized for use in the European Union (see Annex II to Regulation (EC) No 1333/2008) under the E-number 445. The applicable EU specifications (Regulation (EU) No 231/2012) refer to "aged pine stumps" without specifying any concrete species of pine trees as a source for wood rosin extraction.

E 445 is mainly used as an emulsifier and stabilizer in non-alcoholic flavored cloudy drinks. It can also be used as an emulsifier and stabilizer in cloudy spirit drinks and flavored cloudy alcoholic drinks containing less than 15% of alcohol (up to 100 mg/l). Other uses are for the surface treatment of citrus fruit (up to 50 mg/kg) and for printing on personalized and/or promotional hard-coated confectionery products (up to 320 mg/kg).

Glycerol esters of wood rosins are permitted for use also in other countries (to our knowledge e.g. in Canada, China, Mexico, South Africa and the USA).

9. List of data available:

Toxicological data

JECFA assessed GEWR (INS 445(iii)) in 2013 and allocated an ADI of 0-25 mg/kg bw. Chemical equivalence is sought between Resins 8WR- glycerol esters of wood rosins derived from other pine species and GEWR (INS 445-iii) as specified in the current JECFA specification (2013) which restrict the source material to *Pinus palustris* (longleaf) and *Pinus elliottii* (slash) species.

Preliminary technical (IR Spectrum) tests conducted on JECFA specified (GEWR) and Resins 8WR-“glycerol esters of wood rosins” indicate the “monograph” similarities between the two compounds.

Technological data

- a. Submission of the certificate of analysis for wood rosin supplied by the Greek company 'Megara Resins Anastasios Fanis SA'
- b. Submission of the preliminary test (Technical Service Bulletin) of comparative analysis of Resina 8WR (GLYCEROL ESTERS WOOD ROSINS) to JECFA specified (GLYCEROL ESTER WOOD ROSIN).

10. Date on which data could be submitted to JECFA.

Final results of the chemical equivalency studies between the two test materials should be available by the date of the CCFA49 meeting.

Analytical Lab, conducting the chemical equivalence studies, is GLP and ISO 17025 certified.