

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):	POLIVINYL ALCOHOL (PVOH) - CAS 9002-89-5
Question(s) to be answered by JECFA (Kindly provide a brief justification of the request in case of re-evaluations)	Request to change the JECFA monograph: solubility of PVOH in ethanol from “sparingly soluble in ethanol” to “practically insoluble or insoluble in ethanol (≥ 99,8 %)”

1. Proposal for inclusion submitted by: JONES DAY, Rue de Régence 4, 1000 Brussels
2. Name of substance; trade name(s); chemical name(s): Polyvinyl alcohol
3. Names and addresses of basic producers: Nippon Synthetic Chemical Industry
4. Has the manufacturer made a commitment to provide data? Yes
5. Identification of the manufacturer that will be providing data (Please indicate contact person): Ales Bartl, email: abartl@jonesday.com, Tel: 0032 2 645 1452
6. Justification for use: Existing food additive (INS 1203) used as a glazing agent or thickener
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): 13.6 Food supplements, 45000 mg/kg
8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies));

Approved for use in the EU in food supplements supplied in a solid form permitted at 18000 mg/kg only in capsule and tablet form

9. List of data available (please check, if available)

Toxicological data

- (i) Metabolic and pharmacokinetic studies
- (ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
- (iii) Epidemiological and /or clinical studies and special considerations
- (iv) Other data

Technological data

- (i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)
- (ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

The Institute for Health and Consumer Protection (IHCP) of the European Commission's Joint Research Centre carried out solubility studies of polyvinyl alcohol to update the solubility data of the existing Union specifications vis-à-vis its solubility in ethanol.

Intake assessment data

- (i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used
- (ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Other information (as necessary/identified)

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

Immediately

Data supporting the request:

- two copies of solubility tests

- copy of Regulation (EU) 2015/463 of 19 March 2015 amending Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for polyvinyl alcohol (E 1203)