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 Compound(s):** Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer

**Question(s) to be answered by JECFA** (kindly provide a brief justification of the request in case of re-evaluations)

<table>
<thead>
<tr>
<th>Question(s) to be answered by JECFA</th>
<th>Safety assessment and establishing of specification and INS number</th>
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1. Proposal for inclusion submitted by:
   Germany

2. Name of compound; trade name(s); chemical name(s):
   Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer; Kollicoat® IR; Polyvinyl alcohol-polyethylene glycol-graft-co-polymer

3. Names and addresses of basic producers:
   BASF SE, D-68623 Lampertheim, Germany

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):
   Brigitte Grothe
   Senior Manager Global Regulatory Affairs / Human Nutrition, BASF SE
   Phone: +49 621 60-44322
   Fax: +49 621 60-6644322
   E-Mail: brigitte.grothe@basf.com

6. Justification for use:
   PVA-PEG graft co-polymer is used mainly for the production of instant-release coatings for food supplements tablets/capsules. The special advantages of PVA-PEG graft co-polymer lies in its enormous flexibility, low viscosity and rapid rate of dissolution.

7. Food products and food categories within the GSFA in which the compound is used as a food additive or as an ingredient, including use level(s):
   PVA-PEG graft co-polymer-based film coating formulations are applied to food supplement tablets/capsules. PVA-PEG graft co-polymer may constitute up to 5.0% of the weight of the tablet/capsule.

8. Is the compound currently used in food that is legally traded in more than one country? (please identify the countries); or, has the compound been approved for use in food in one or more country? (please identify the country(ies))
   PVA-PEG graft co-polymer is applied for use in food supplements in the European Union; decision is pending. Furthermore PVA-PEG graft co-polymer is world-wide used in several pharmaceutical applications at comparable use concentrations.
9. List of data available (please check, if available)

**Toxicological data**

(i) Metabolic and pharmacokinetic studies
   - Study of the Bioavailability after Oral Administration in Rats (BASF 2001)

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
   - Prenatal Development Toxicity Study in Wistar Rats Oral Administration (Gavage) (BASF 2002),
   - Salmonella Typhimurium / Escherichia Coli Reverse Mutation Assay (Standard Plate Test and Preincubation Test) (BASF 2000),
   - In Vitro Gene Mutation Test in LS178Y Mouse Lymphoma Cells (TK+/- Locus Assay, Microwell Version) (BASF 2000),
   - Cytogenetic Study in Vivo in the Mouse Micronucleus Test After Two Intraperitoneal Administrations (BASF 2001),
   - Chronic Oral Toxicity in Beagle Dogs Administration in the Diet for 9 Months (BASF 2002),
   - Subchronic Toxicity in Wistar Rats Administration in Drinking Water for 3 Months (BASF 2001)
   - Prenatal Developmental Toxicity Study in Himalayan Rabbits Oral Administration (Gavage) (BASF 2002),
   - Fertility and Pre-/Postnatal Developmental Toxicity Study in Wistar Rats Oral Administration (Gavage) (BASF 2003),
   - Acute Oral Toxicity in Rats (BASF 2000),
   - Acute Dermal Irritation / Corrosion in Rabbits (BASF 2000),
   - Acute Eye Irritation in Rabbits (BASF 2000)

(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

**Technological data**

(i) Specifications for the identity and purity of the listed compounds (specifications applied during development and toxicological studies; proposed specifications for commerce)
   - Available

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed compound
   - Available

**Intake assessment data**

(i) Levels of the listed compound used in food or expected to be used in food based on technological function and the range of foods in which they are used
   - Application levels in food supplements available

(ii) Estimation of dietary intakes based on food consumption data for foods in which the compound may be used.
   - Available

*Other information as necessary*
10. Date on which data could be submitted to JECFA:
   Immediately