Annex 2

FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

Name of Substance(s):	Silicon Dioxide, Amorphous
Questions to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	Request for a safety re-evaluation of Silicon Dioxide, Amorphous (INS 551), including toxicological evaluation, exposure assessment, and specifications. JECFA last conducted a safety assessment of Silicon Dioxide, Amorphous (INS 551) in 1985, resulting in an assigned acceptable daily intake (ADI) of "not specified" for silicon dioxide and certain silicates. Evaluations in 2015 and 2017 were considered for specification only. Extensive physical, chemical, and toxicological data have been developed since the last safety assessment and, in consideration of the global use of silicon dioxide as a food additive and advances in risk assessment of particles, a timely safety re-evaluation would provide international assurance for the substance's continued use.

1. Proposal for inclusion submitted by:

   International Food Additives Council (IFAC)
   529 14th Street NW, Suite 1280
   Washington, DC 20045
   USA

2. Name of the substance; trade name(s); chemical names(s), IUPAC name, C.A.S number (as applicable):

Name of the substance:	Silicon Dioxide, Amorphous
Synonyms:	Silica; INS No. 551; Synthetic Amorphous Silica (SAS); Silicon dioxide
Trade names:	AEROSIL®, CAB-O-SIL®, DARACLAR®, FLO-GARD™, GASIL®, HDK®, IBERSIL®, NEOSYL®, PERKASIL®, RxCIPIENTS®, SILCRON®, SILICA VP, SIPERNAT®, SYLOBLANC®, SYLODENT®, SYLOID®, Tixosil®, TRISYL®, Zeofree®, Zeothix® (list not exhaustive)
Chemical name(s):	Silicon dioxide, chemically prepared
IUPAC name:	Dioxosilane
CAS Number:	7631-86-9 112945-52-5 (pyrogenic silica) 112696-00-8 (hydrated silica)

3. Names and addresses of basic producers

   Cabot Performance Materials Belgium/Cabot Corporation, Boston, USA
   Evonik Resource Efficiency GmbH, Hanau-Wolfgang, Germany
   GRACE GmbH, Worms, Germany/W.R. Grace & Co., Columbia, Maryland, USA

IQESIL S.A., Zaragoza Spain
PPG, Pittsburgh, Pennsylvania, USA/ PPG Industries Chemicals B.V., Delfzijl, The Netherlands
PQ LLC, US/PQ Silicas UK Ltd, Warrington, UK
Solvay S.A., Bruxelles, Belgium
Wacker Chemie AG, Munich, Germany

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

   The basic producers identified in item 3 above will be providing data through their representative trade associations, as follows:

   Association of Synthetic Amorphous Silica Producers (ASASP), a Cefic Sector Group
   Contact: Caroline Andersson, CAN@cefic.be

   Synthetic Amorphous Silica and Silicate Industry Association (SASSI)
   Contact: Joel F. Carpenter, joel.f.carpenter@gmail.com

5. Justification for use:

   Silicon dioxide (INS 551) is permitted in a variety of Food Categories as an anticaking agent, antifoaming agent, and carrier. INS 551 provides anti-caking properties to prevent lumping of powdery foodstuffs. INS 551 also serves as a carrier to assist in the handling and applications of for use in food additives, food enzymes, flavorings, and nutrients.

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

   Silicon dioxide, amorphous is listed in Table 3 of the General Standard for Food Additives (GSFA), as an additive permitted for use in food in general in accordance with good Manufacturing Practice (GMP). It is also listed in the following GSFA food categories.

Category No.	Category	Use Level
1.6.1	Unripened cheese	GMP
1.6.2.1	Ripened cheese, includes rind	GMP
1.8.2	Dried whey and whey products, excluding whey cheeses	10,000 mg/kg
11.1.2	Powdered sugar, powdered dextrose	15,000 mg/kg
12.1.1	Salt	GMP
12.1.2	Salt substitutes	GMP
12.2.1	Herbs and spices	GMP
13.2	Complementary foods for infants and young children	2000 mg/kg
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	GMP

7. 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))

   Silicon dioxide, amorphous is used in all countries that legally permit use of GFSA-listed food additives. Silicon dioxide, amorphous, is also explicitly approved under the food additive laws

and regulations in many jurisdictions, including Australia, Canada, China, European Union, Japan, United Kingdom, and the US.

8. Are you aware of any current impediments in international trade due to lack of JECFA evaluation and/or Codex standard? If so, please provide details.

   As indicated in item 9 below, global regulatory authorities continue to evaluate the safety of silicon dioxide for use as a human and animal food additive, in response to specific industry petition or as part of on-going safety re-evaluations. In some instances, questions regarding the particle size of silicon dioxide have affected the evaluation of the available toxicity data. Similar questions for titanium dioxide led to the withdrawal of its food additive approvals in several jurisdictions. The resulting trade disruptions are cited as significant basis for JECFA's current prioritization of its safety reevaluation of titanium dioxide (see Replies to CL 2021/61-FA at the 52nd Session of the Codex Committee on Food Additives). Significant efficiency is presented by leveraging already planned safety assessment of titanium dioxide and concurrently reviewing amorphous silicon dioxide, given the similarities presented between the substances and their uses.

9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.

   The European Food Safety Authority (EFSA, Via Carlo Magno 1A, 43126 Parma, Italy) is currently re-evaluating INS 551 as part of the ongoing food additive re-evaluation process in Europe.

   The US Food and Drug Administration (FDA, Center for Veterinary Medicine, 12225 Wilkins Avenue, Rockville, Maryland 20852, USA) evaluated silicon dioxide in 2019 (Food Additive Petition (FAP) 2308) for use as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal food components, for example, ingredients, intermediate premixes, premixes, supplements, or concentrates at an amount not to exceed 2% by weight of complete animal food. This evaluation included both human and target animal safety assessments.

   In 2021-2022, FDA (Center for Food Safety & Applied Nutrition, 5001 Campus Drive, College Park, Maryland, 20740) evaluated an industry notification (GRN No. 996) regarding the generally recognized safety of synthetic amorphous silica (SAS) for use as a carrier to deliver and improve the perception of sweetness of white sugar at levels up to 0.30 g/100 g.

10. Please provide details if this food additive is of particular relevance to the livelihood and the food safety in developing countries

    INS 551 is globally relevant to food safety. For developing countries, INS 551 is critical in ensuring the safety of spices originating from such countries as well as powdered infant formulae that are available in such countries.

11. Please indicate the type of data that are available in the table below.
    Ensure that the available data are directly relevant to the substance of interest in this request. In particular, for substances obtained from natural resources, characterization of the products in commerce and a relevant set of biochemical and toxicological data on such products are essential for JECFA to develop a specifications monograph and the related safety. Such data/information typically include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances; ect.

	Data available? (Y/N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y (Metabolic studies)
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y (Studies and summaries on these toxicological endpoints are available and can be provided)
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	Y (Epidemiological studies evaluating inhalation route)
(iv) Other data (please specify)	N
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y (JECFA Monograph for Silicon Dioxide, Amorphous (2017) Physical (IR) or Chemical identification test)
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y (Description of the manufacturing process, efficacy)
Dietary exposure assessment data	
(i) Levels of the listed substance used in food or expected to be used in food based on the technological function and the range	Y (Food legislation, food categories and allowed max. concentrations)
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used	Y (EFSA Scientific Opinion Re-evaluation of Silicon dioxide (2017), section 3.4.4 EU Consumption database)
Other information: *(please specify)*	

12. Specify earliest date when data can be made available to JECFA. (Data shall only be submitted in response to a JECFA call for data; do NOT include any data intended for JECFA to this form.)

All information and data identified in response to Item 11 is currently available and can be submitted upon publication of a JECFA call for data.