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):	**Potassium polyaspartate**
Question(s) to be answered by JECFA *(Provide a brief justification of the request in case of re-evaluations)*	Safety evaluation and establishment of specification when used as a stabilizer.

1. **Proposal for inclusion submitted by:**

Ministero delle politiche agricole alimentari e forestali
Ministry of Agricultural Food and Forestry Policies
Directorate General of the European Union and International Policies
Italian Codex Contact Point
Via XX Settembre, 20
00187 Roma - Italy
Phone: +39 06 46654058
Email: piue2.codex@politicheagricole.it

2. **Name of substance; trade names; chemical name:**

Name of substance: Potassium polyaspartate

Trade names: A-5D , Zenith

Chemical name: L-Aspartic Acid, Homopolymer, potassium salt

E number E456

CAS number 64723-18-8

3. **Names and addresses of basic producers**:

Manufacturer:

NANOCHEM SOLUTIONS

6502 S. Archer Rd., Bedford Park IL 60501

ILLINOIS- USA

Marketer:

ESSECO S.R.L.

Via San Cassiano 99,

28069 Trecate (NO) – Italy

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

NanoChem Solutions commits to provide data to support the proposal for inclusion of potassium polyaspartate in the list of substances to be evaluated by JEFCA.

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

NANOCHEM SOLUTIONS

6502 S. Archer Rd., Bedford Park IL 60501

ILLINOIS- USA

Attn: Grace Fan, General Manager

Tel: + 17 (847) 612-7404

E Mail: lgfan@nanochems.com

6. **Justification for use:**

Potassium polyaspartate is a new food additive to be used as a stabilizer against tartrate crystal precipitation in wine. Thanks to its characteristics of strong effectiveness also in highly unstable wines, stability in wine over time, and absence of sensory effects, potassium polyaspartate represents an effective, environmental friendly, inexpensive, and user friendly additive for tartaric stabilization of wine.

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):**

Food category: 14.2.3, Grape wines

Max. use level : 100 mg/L

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))**

Potassium polyaspartate is currently used in countries of the European Union (EU)

EU: food additive Regulation (EC) No 1333/2008, Annex II amended by Commission Regulation (EU) 2017/1399 of 28 July 2017

EU: oenological practices Regulation (EC) No 606/2009 Annex IA amended by the Regulation (EU) 2017/1961 of 2 August 2017

Other countries: product registration in progress / in preparation

In 2016 OIV (Organisation International de la Vigne e du Vin) adopted the Resolution OIV-Oeno-543-2016 recommending the use of potassium polyaspartate for wine stabilisation. OIV is an international intergovernmental organisation of recognised competence in international harmonisation of practices and standards in the field of vine and wine.

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

Toxicological data

The results of toxicological studies show as potassium polyaspartate is negligible absorbed, it does not affect gut cells integrity and it does not induce any activation of the immune system. It is not mutagenic or genotoxic and it does not cause any toxic effect, even in case of repeated dosing (90 days NOAEL = 1000 mg/kg body weight /day, maximum tested dose). Thus it can be concluded that the proposed use of potassium polyaspartate as food additive for tartaric stabilization in wine does not represent a safety concern.

The EFSA opinion on Potassium polyaspartate provide details on the toxicological assessment.

(i) Metabolic and pharmacokinetic studies

See EFSA scientific opinion chapter 3.3.1. Quotation:

"The Panel considered that there was negligible absorption of polyaspartate"

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies

Toxicity & carcinogenicity

See EFSA scientific opinion chapter 3.3.3 and 3.3.4. Quotations:

"Based on the findings of this study, the authors report a no observed adverse effect level (NOAEL) of potassium polyaspartate (A-5D K/SD)"

"In line with the current Guidance (EFSA ANS Panel, 2012), the data from the repeated dose 90-day oral toxicity study in rats conducted with potassium polyaspartate (A-5D K/SD) and from Tier 1 toxicokinetics did not trigger additional testing for chronic toxicity and carcinogenicity."

Reproductive toxicity, and developmental toxicity studies

see EFSA scientific opinion chapter 3.3.5. Quotation:

"In line with the current Guidance (EFSA ANS Panel, 2012), the data from the repeated dose 90-day oral toxicity study in rats conducted with potassium polyaspartate (A-5D K/SD) and from Tier 1 toxicokinetics did not trigger additional testing for reproductive and developmental toxicity."

Genotoxicity

See EFSA scientific opinion, chapter 3.3.2. Quotation:

"The Panel considered that, in line with its guidance 'In cases where all in vitro endpoints are clearly negative in adequately conducted tests, it can be concluded with reasonable certainty that the substance is not a genotoxic hazard' (EFSA ANS Panel, 2012)."

Neurotoxicity

See EFSA scientific opinion chapter 3.3.7. Quotation:

"The Panel considered that potassium polyaspartate (A-5D K/SD) has no neurotoxicity."

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

The relevant data from Tier 1 in vitro absorption, in vitro genotoxicity and subchronic toxicity testing performed with potassium polyaspartate showed no immunotoxicity .
No allergic reaction of sodium salt has been observed. No intolerance reactions is expected.

See also EFSA scientific opinion chapter 3.3.6.

(iv) Other data

Polyaspartic acid risk classification:

- Environmental Protection Agency: No risk reported (EPA 2012)
- International Agency for Research on Cancer: Not listed (IARC 2012)
- National Institute for Occupational Safety and Health: Not listed (NIOSH 2012)
- US Occupational Safety and Health Administration: Not regulated (OSHA 2012)

Technological data

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

Identity of the substance and structural formulae : see EFSA scientific opinion chapter 3.1.1.

Specifications : see EFSA scientific opinion chapter 3.1.2.

(ii)Technological and nutritional considerations relating to the manufacture and use of the listed substance :

See below

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

100 mg/L.

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

see EFSA scientific opinion chapter 3.2.2. Quotation:

"The mean dietary exposure from the proposed typical use level of 200 mg/L ranged from 0.01 to 0.2 mg/kg bw per day in adults up to 0.04 to 0.4 mg/kg bw per day in the elderly. The high-level intake ranged from 0 to 1.0 in adults and from 0.3 to 1.2 mg/kg bw per day in the elderly.

At the proposed ML of 300 mg/L, the mean dietary exposure ranged from 0.02 to 0.4 mg/kg bw per day in adults up to 0.05 to 0.6 mg/kg bw per day in the elderly. The high-level intake ranged from 0 to 1.4 in the adults and from 0.4 to 1.8 mg/kg bw per day in the elderly."

Other information (as necessary/identified)

None

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

Data is available and can be submitted when required.

Attachments:

1. EFSA Scientific Opinion
2. Toxicologic evaluation of potassium polyaspartate (A-5D K/SD):Genotoxicity and subchronic toxicity. C.Galbusera, C.Casalegno, S.Marroncelli, G.Triulzi, J.Santos, E.Corsini, P.Restani - Food and Chemical Toxicology, 2017