Potassium Aluminium Silicate (Mica)

Chemical and Technical Assessment (CTA)

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1. Summary

Potassium aluminium silicate (PAS) was first reviewed at the 74th Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2011) for use as a carrier substrate for pearlescent pigments coated with titanium dioxide and/or iron oxide. Tentative specifications were prepared at the 74th JECFA pending receipt of information such as the preparation and purification of PAS, data on particle size distribution and impurities from five batches of PAS, and information on analytical methods for specifications for PAS. This information was to be made available for the 77th JECFA (2013). While the sponsor did comment on all information requested by JECFA, not all information requested was received. However, enough information was received to revise the specifications.

At the 42nd meeting of the Codex Committee on Food Additives (CCFA), the sponsor requested that JECFA evaluate potassium aluminium silicate (mica) as a carrier substrate for titanium dioxide and/or iron oxide. As indicated by information provided by the sponsor, potassium aluminium silicate is not intended to be used in food itself as a food additive, but rather, will only be used as the compound pigment, known as pearlescent pigment, when titanium dioxide and/or iron oxide have been formed as a coating on its surface through high temperature processes. As a result, all additive use data and the majority of toxicological data provided by the sponsor actually pertain to the pearlescent pigment, and not the material initially requested for analysis, PAS.

The approach taken by the sponsor to evaluate PAS as a carrier for titanium dioxide and/or iron oxide is consistent with the approach taken to regulate pearlescent pigments in the European Union (EU). The EU considers the pearlescent pigment to be a mixture of PAS and one or both of titanium dioxide and iron oxide. As such, the EU relies on the individual safety determinations and specifications for the separate entities of potassium aluminium silicate, titanium dioxide and iron oxide. As indicated in DIRECTIVE 2003/114/EC, potassium aluminium silicate is permitted for use in the EU as a carrier for titanium dioxide and iron oxide, with specifications for the individual substances as provided in European Commission Regulation 231/2012 for potassium aluminium silicate, titanium dioxide and iron oxide.

In the United States of America (USA), instead of considering the carrier substrate PAS and the color titanium dioxide separately, the compound pigment itself, under the name mica-based pearlescent pigments, is regulated under 21 Code of Federal Regulations (CFR) 73.350. As noted in 21 CFR 73.350, only titanium dioxide based pearlescent pigments are currently permitted. A reference is also made in 21 CFR 73.350 requiring that mica used to make the pearlescent pigments must conform to specifications for mica in 21 CFR 73.1496(a)(1).

Under the guiding principles that specifications are intended to apply to the additive as marketed and used in food, as well as represent the substance for which toxicological testing was performed, the 74th JECFA decided to prepare separate specifications for both PAS as well as the actual compound pigment. The name of the monograph used to describe the compound pigment was "Potassium aluminium silicate-based pearlescent pigments" (PAS-BPP). Both sets of specifications prepared at the 74th JECFA were made tentative pending receipt of additional data.

The 77th JECFA will revise the tentative specifications for PAS made at the 74th JECFA in light of the additional information received by the sponsor.

2. Description

PAS is of natural origin and obtained by mining. The sponsor indicates that PAS, which is a form of muscovite mica, has the idealized formula of KAl2[AlSi3O10](OH)2. PAS is not intended to be added to food directly, but rather, used as a carrier substrate in PAS-BPP made with titanium dioxide and/or iron oxide. PAS used in the manufacture of pearlescent pigments is not chemically modified, but is washed and ground to specific particle size. The sponsor has not indicated the precise size of the PAS used to produce the pearlescent pigments; however, they note that PAS particle size is on the same order of magnitude as the pearlescent pigments which may range in size from 1-500 micrometers.

3. Method of Manufacture

PAS is a natural mineral and is obtained by mining. For its use as a carrier substrate for titanium dioxide and/or iron oxide in PAS-BPP, it is not chemically modified, but is washed and ground to desired particle size.

4. Characterization

4.1 Composition

PAS is more commonly referred to as mica, or, more specifically, muscovite mica, and has an idealized formula of $KAl_2[AlSi_3O_{10}](OH)_2$.

4.2 Impurities

The sponsor has recommended specifications for a number of potential metal impurities in PAS including arsenic, barium, cadmium, chromium, copper, mercury, nickel, lead, antimony and zinc. These quality control metal specifications are being recommended due to the natural origin of the PAS used to make PAS-BPP. The metal limits recommended by the sponsor are identical to those listed for PAS in European Commission Regulation 231/2012. The sponsor provided testing data for the 10 metals from four batches of PAS.

4.3 Stability

Information regarding the stability of PAS was not provided by the sponsor as PAS is not itself used in food, but rather only when used as part of PAS-BPP. The sponsor has provided some information arguing for the stability of PAS-BPP which is addressed in the CTA for PAS-BPP.

4.4 Rationale for Proposed Specifications

The proposed specifications were developed from information provided by the sponsor.

It is typical to include identification tests in the specification monograph that allow for determination of the presence of components of the additive. In this way, identification tests for the presence of silicon and aluminium, which are component parts of PAS, have been recommended. The sponsor was requested to comment on the need for such identification tests for PAS. They responded that such identification tests are not necessary, as PAS itself is not placed on the market itself, but rather, only as a component of PAS-BPP. At the 77th meeting, after deliberating on the sponsor's comments, the Committee determined that identification tests for silicon and aluminium were needed in the specifications monograph.

The sponsor has proposed specification limits for 10 metals (arsenic, barium, cadmium, chromium, copper, mercury, nickel, lead, antimony and zinc), some of which are typical in JECFA monographs (e.g., arsenic, lead and mercury), but others which are not typically seen in JECFA monographs. Specifications for the other metals may be necessary due the natural source of PAS. The sponsor was asked to comment on the need for the non-traditional metal specifications. They indicated that the 10 metals are those tested for to be in compliance with the specifications set in European Commission Regulation 231/2012 for PAS. They indicated, however, that they believe sufficient quality control would be achieved with the inclusion of specifications for mercury, lead, arsenic and cadmium.

The conditions proposed for the determination of the potential metal impurities is an extraction using 0.5 M hydrochloric acid rather than a complete digestion of the PAS particles. The sponsor argues that PAS will not be used in food directly, but only as a part of PAS-BPP. In addition, they note that PAS-BPP particles will not be digested upon consumption, but rather only subject to extraction by stomach acids. They argue that boiling the PAS-BPP particles with 0.5M hydrochloric acid is more extreme than the conditions encountered in the body during digestion, and therefore is suitably conservative.

A loss on drying specification of not more than 0.5% is included as well as an assay for PAS of not less than 98%. These specifications are taken directly from the specifications found for PAS in the European Commission Regulation 231/2012.

4.5 Analytical Methods

Some of the analytical methods proposed by the sponsor for PAS are comparable to tests included in the Combined Compendium of Food Additive Specifications for identity and purity (FAO JECFA Monographs 1, Volume 4, 2006). Other methods recommended by the sponsor are not typical JECFA methods, and may not have been used before in JECFA specification monographs. For example, the sponsor has recommended X-ray fluorescence (XRF) and X-ray diffraction (XRD) for the Assay for PAS, and Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) for determination of lead and seven other metals. The sponsor was asked if less expensive methods could be used (in line with JECFA's desire to only include analytical methods that are accepted internationally but also are generally available in most laboratories at a reasonable cost). The sponsor answered that they are only able to provide information on the methods validated for use in their laboratories.

4.5.1 Identification tests for silicon and aluminium

Although the sponsor indicates that identification tests are not necessary for PAS, we have proposed identification tests for silicon and aluminium. These tests are based on the ICP-AES assay method for PAS, and use the analytical lines for Al (396.15 nm) and Si (251.611 nm).

4.5.2 Loss on drying

Loss on drying is determined as recommended in Volume 4 of the FAO JECFA Monographs with the PAS sample heated at 105°C for 2 hours.

4.5.3 Assay for PAS

The sponsor has submitted information regarding the use of an XRF technique for the determination of the Assay for PAS. However, JECFA believes that XRF is not commonly available in all international testing laboratories. As a result, the Committee recommends the use of ICP-AES using alkali fusion for sample preparation to determine the amount of aluminium in the PAS sample. The percentage of PAS in the sample is then determined using the idealized formula for PAS.

4.5.4 Impurities soluble in 0.5 M hydrochloric acid

The sponsor provided individual specifications for barium, cadmium, chromium, copper, nickel, lead, antimony and zinc based on extraction with 0.5 M hydrochloric acid. Except for arsenic, the sponsor recommended analysis with Inductively Coupled Plasma Mass Spectrometry (ICP-MS). JECFA believes that ICP-MS is a technique that is not available in many international laboratories.

Therefore, a recommendation is made in the monograph to determine arsenic using an AAS (Hydride generation) technique; antimony, barium, chromium, copper, nickel and zinc by ICP-AES technique; lead and cadmium using an AAS (Electrothermal atomization) technique; and mercury using an AAS (Cold vapour generation) technique.

5. Functional Uses

5.1 Food Categories and Use Levels

The sponsor has indicated that PAS will not be used directly in food, but rather, only as part of PAS-BPP. As a result, it is not appropriate to list food categories and use levels for PAS as it will not be introduced into food apart from its use in PAS-BPP. The food categories and use levels for PAS-BPP are listed in the CTA for PAS-BPP. However, the categories can broadly be described as confectionary, candy, decorations and beverages.

6. Reactions and Fate in Foods

6.1 Determination of Levels in Food

As PAS will not be incorporated directly into food, but rather, only as part of BAS-BPP, the sponsor has not provided information regarding the determination of PAS levels in food. This topic is discussed in the CTA for BAS-BPP.

7. References

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