United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Kaolin

Handling/Processing

Identification

Chemical Names:
$Al_2Si_2O_5(OH)_4$; aluminum silicate dihydrate; aluminum silicate hydroxide; hydrated aluminum silicate

Other Name:
argilla bianca; Bolus alba; China clay; colloidal kaolin; French white clay; heavy kaolin; kaolin clay; kaolinite; light kaolin; white cosmetic clay

Trade Names:
1149 USP; Kaolin KR USP; Surround® WP

CAS Numbers:
1332-58-7

Other Codes:
E559
EC#310-194-1
RTECS#GF1670500

Summary

This limited scope technical report provides updated information to the National Organic Standards Board (NOSB) to support the sunset review of kaolin, listed at 7 CFR 205.605(a)(15). This report focuses on uses of kaolin in organic processing and handling, as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Kaolin was included on the National List of Allowed and Prohibited Substances (hereafter referred to as the “National List”) with the first publication of the National Organic Program (NOP) Final Rule (65 FR 80548 December 21, 2000). The NOSB has continued to recommend its renewal in 2007, 2012, 2017, and 2022 (NOSB, 2009, 2010, 2015, 2020).

As kaolin is listed at 7 CFR 205.605(a), only nonsynthetic forms are allowed. Kaolin is listed without further annotation limiting its use. The FDA considers kaolin to be Generally Recognized as Safe (GRAS) (21 CFR 186.1256) as an indirect food additive, and it is a common ingredient in paper and paperboard materials that processors use for food packaging.[1]

In practice, kaolin appears to have niche uses in organic food production. We base this conclusion in part on public comments submitted in support of the sunset reviews of kaolin during the 2015 and 2020 NOSB meetings. Consequently, we found limited information specific to the evaluation questions requested. Based on these comments and other public sources, kaolin is used in organic production:

- as an ingredient in personal care products[2]
- as a filtration component in the manufacture of juices

In 2015, a representative from Smucker Natural Foods stated that kaolin was essential for filtering organic juices (Dietz, 2015). Other commenters noted its use to prevent sunscald in fruit, a use that is not related to the handling scope. The Juice Products Association provided comments in 2015 and 2020, stating that kaolin was used in the production of juices, juice beverages, and juice products, but without further specifics (Juice Products Association, 2015, 2020).

In 2020, one certifier commented that six operations listed kaolin on their OSP for personal care products (California Certified Organic Farmers, 2020). Viseras et al (2021) describe kaolin as a filler, additive, and functional ingredient in personal care and cosmetic products. Another certifier stated that three operations listed kaolin on their OSP (Pennsylvania Certified Organic, 2020); however, they did not specify how kaolin was used.

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[1] The FDA describes indirect food additives as follows: “In general, these are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. Indirect food additives mentioned in Title 21 of the U.S. Code of Federal Regulations (21 CFR) for use in food-contact articles include adhesives and components of coatings (Part 175), paper and paperboard components (Part 176), polymers (Part 177), and adjuvants and production aids (Part 178). Currently, additional indirect food additives are authorized through the food contact notification program. In addition, indirect food additives may be authorized through 21 CFR 170.39” (US FDA, 2024).

[2] According to the USDA, personal care products (as well as cosmetics and body care products) are eligible for USDA organic certification and labelling if they contain agricultural ingredients and can otherwise meet USDA organic standards (USDA, 2008).

Some uses reported for kaolin in the past do not require that kaolin be listed at § 205.605. For example, the authors of the 1995 TAP report on kaolin and bentonite note that kaolin is used in paper and paperboard materials that come in contact with food (NOSB, 1995). However, the organic regulations do not require substances used in food packaging to be reviewed under the handling/processing scope. The USDA organic regulations only specify that packaging materials, storage containers, and bins not be treated with synthetic fungicides, preservatives, or fumigants (§ 205.272):

> (b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:
>
> > (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;
> >
> > (2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

The 1995 TAP report also states that kaolin can be used as an anti-caking agent in processed food. While kaolin can function as an anti-caking agent (United States Pharmacopeial Convention, 2008), current FDA regulations do not include kaolin as a food additive for *direct* addition to food for human consumption as an anti-caking agent (21 CFR 172). Furthermore, we found no publicly available evidence that kaolin is commonly used as an anti-caking agent in human foods at the present time.

Additional reported uses of kaolin relevant to the processing and handling scope include:

- post-harvest pest control of stored grains (El-Shewy et al., 2024; Golob, 1997)
- clarification of fruit wines (Awe, 2018; Minh, 2022)
- filtration of seed oils (Wang et al., 2021)

As a post-harvest pest control material, kaolin is allowed because of its inclusion at § 205.605(a), but also because it conforms to the requirements noted within NOP 5023 (NOP, 2016). In NOP 5023: *Guidance, Substances Used in Post-Harvest Handling of Organic Products*, the NOP describes the compliance of materials used for post-harvest pest control. Producers can use natural (nonsynthetic) substances (such as kaolin) that are allowed for use in crop production as a post-harvest handling material, regardless of whether they are present at § 205.605(a).

Background

"Kaolin" is a generic term with multiple levels of meaning in common usage (Dill, 2016; King, 2009; Kogel, 2014; Murray, 2007; Murray & Keller, 1993).

- In clay science, kaolins are a particular group of hydrated aluminum silicate minerals with the formula $Al_2Si_2O_5(OH)_4$ and a simple structure in which each layer comprises one silica sheet and one alumina sheet held together by shared hydroxyl groups (King, 2009; Murray, 2007).[3] Kaolinite is the most abundant of the kaolin minerals.
- More generally, kaolin refers to a type of pale-colored clay rock that is rich in kaolinite. Kaolin clays are formed by weathering and/or hydrothermal alteration of granites and rhyolites. Kaolin is common worldwide and is mined on almost every continent (Dill, 2016; Kogel, 2014; Murray & Keller, 1993).

Kaolin clay deposits contain a wide variety of other minerals (such as iron oxides, mica, and quartz) and organic (carbon-based) material in varying proportions (Murray, 2007). Kaolin products undergo a wide range of treatments, depending on the composition of the mined mineral source and the product's intended application (Schroeder, 2018). Treatments range from simple crushing, sieving, and water washing to sophisticated refinement techniques such as magnetic separation, delamination, and chemical removal of impurities.[4] Manufacturers use both wet and dry processing methods to produce highly purified, fine-grained kaolinite powder without altering its natural physical and chemical properties (Murray, 2007). Such kaolin products are nonsynthetic, nonagricultural materials, consistent with kaolin's listing at 7 CFR 205.605(a)(15).

[3] This describes the chemically bound water present between the alumina and silica sheets.
[4] Kaolin particles naturally consist of stacked layers, or plates. *Delamination* separates these stacks into individual plates.

Refined kaolin encompasses a range of particle sizes. Nano-size clay particles (i.e., those ≤100 nm in diameter) are abundant in nature and can be produced using methods that do not fundamentally alter the properties of the mineral (Deshmukh et al., 2023). Tan et al. (2017) analyzed the particle size distribution of a dry kaolinite powder frequently used as a reference mineral. They reported that 10-15% of the particles were smaller than 0.1 μM (100 nm), thus falling into the nanoscale range. In practice, kaolin manufacturers do not routinely evaluate the particle size distribution for the fraction smaller than 2 μM (Tan et al., 2017), so the presence or quantity of nano-size clay particles in a given product is likely to be unknown. NOP Policy Memorandum 15-2 (NOP, 2015), which addresses the use of nanotechnology in organic production and handling, notes that nanomaterials can occur naturally or as byproducts of processing, such as homogenization and milling. Such “incidental” nanomaterials, including the nanoscale particles that may be present in nonsynthetic kaolin products, are not prohibited in organic processing and handling (NOP, 2015).

The authors of the 1995 TAP report on kaolin and bentonite (NOSB, 1995) state that kaolin “can be calcined in a kiln to produce a fine powder,” but they do not further distinguish between calcined and non-calcined kaolin. Calcination is an additional processing step that improves the brightness and opacity of kaolin for uses in paper filling and coating and other specialized applications (Murray, 2006). Metakaolin, formed from calcining kaolin, has a different chemical structure. As such, we consider it a different material than kaolin.

To calcine kaolin, manufacturers heat kaolin ($Al2Si_2O_5(OH)_4$; CAS No. 1332-58-7) in a kiln or calciner. Dehydroxylation (the release of hydroxyl groups) is the first step of calcination and typically occurs at temperatures between 400 °C–650 °C (Zunino & Scrivener, 2024). Kaolin is a 1:1 ratio clay, with a stacking crystal structure where each layer includes one silicate and one aluminate sheet (Zunino & Scrivener, 2024). The calcination of kaolin leads to the destruction of the kaolin sheet structure, creating an amorphous material, metakaolin ($Al_2Si_2O_7$; CAS No. 15123-81-6) (Daou et al., 2020). The degree to which this conversion happens depends on the specifics of the heating conditions (*e.g.,* heating rate and maximum temperature). In one study, scientists found that above 550 °C only metakaolin remained (Daou et al., 2020).

According to an ACA best practices guide, metakaolin produced from calcining kaolin “at a high temperature” is synthetic (Accredited Certifiers Association, 2024). Furthermore, kaolin products have a high risk of being classified as synthetic due to acid treatment (Accredited Certifiers Association, 2024). However, the ACA guidance does not specify a temperature range, nor does it distinguish between (clearly nonsynthetic) hydrous kaolin and calcined kaolin that has not been heated sufficiently to produce metakaolin. As a synthetic material, metakaolin is outside the scope of this report and is excluded from the following discussion. Further, we note that whether a given kaolin product is or is not calcined may not always be obvious to organic processors and handlers. In our limited survey of commercial kaolin products, we found that some products labeled with CAS No. 1332-58-7 (properly applied to kaolin) were described elsewhere as calcined kaolin.

Evaluation Questions

<u>Evaluation Question #6:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance [7 CFR 205.600(b)(5)].
The FDA establishes “action levels” for poisonous or deleterious substances that are unavoidable in human food and animal feed (US FDA, 2000). These include aflatoxin, cadmium, lead, polychlorinated biphenyls (PCBs), and many other substances. The FDA uses different action level tolerances for these substances, depending on the commodity. Commodities are largely food items; however, the FDA also includes tolerances for ceramic and metal items, such as eating vessels and utensils. Kaolin is not included on the list of commodities with action levels (US FDA, 2000).

The Food Chemicals Codex specifies limits on impurities in kaolin as: 10 ppm arsenic and 10 ppm lead (United States Pharmacopeial Convention, 2008). The Food Chemicals Codex does not provide specific limit values for any additional heavy metals or contaminants in kaolin. However, the Select Committee on GRAS Substances recommended the FDA add an upper limit for cadmium for food grade kaolin (Select Committee on GRAS Substances (SCOGS), 1977).

Heavy metals, especially lead and cadmium, are often present in raw, whole kaolin materials, sometimes exceeding levels regarded as safe for consumption (Bonglaisin et al., 2022; Hernández et al., 2019). We surveyed heavy metals lab reports from products composed primarily of kaolin, previously reviewed by OMRI. Amongst this limited subset of data, there were two kaolin materials that exceeded the FCC tolerances for arsenic and lead.

Evaluation Question #7: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity [7 U.S.C. 6517(c)(1)(A)(i) and 7 U.S.C. 6517(c)(2)(A)(i)].

Kaolin deposits occur worldwide (Kogel, 2014; Murray, 2006). As with other extractive industries, kaolin mining heavily impacts sensitive landscapes and ecosystems (Siqueira-Gay et al., 2022; Zapico et al., 2020). Impacts of kaolin manufacture on terrestrial and aquatic environments and biodiversity are discussed below. We found nothing of note concerning harmful effects of kaolin use.

Effects on terrestrial environments

Mining companies extract kaolin clay mainly from near-surface deposits using open-pit methods (Kogel, 2014; Schroeder, 2018). Open-pit mining heavily modifies large sections of the landscape, removing vegetation and soil and degrading the soil structure (Oliveira et al., 2022). Workers then process the raw clay either on- or off-site, leaving waste materials that may contain heavy metals and other contaminants (Jordão et al., 2002b; Nguyễn et al., 2021; Silva et al., 2003; Xiao et al., 2024).

Mining and quarrying inevitably damage biodiversity and ecosystem services. In terrestrial ecosystems, the soil, vegetation, and animal communities are closely interdependent, making it impossible to return degraded land to its original state (Salgueiro et al., 2020). Kaolin mining destroys the soil profile and alters soil chemistry (Lane et al., 2020; Oliveira et al., 2022).[5] Nguyen et al. (2021) analyzed soil samples near mining sites, including those for kaolin, and concluded that soil can be contaminated with elevated levels of trace metals that persist, including zinc, copper, and lead.

Kaolin mining generates large amounts of waste materials (Palumbo-Roe & Colman, 2010; Schwanke et al., 2022). According to Palumbo-Roe & Colman (2010), kaolin clay mining in England generates about 10 million tonnes of waste per year, with a 9:1 ratio of waste to extracted kaolin clay. The waste produced is generally composed of coarse sand and rock that may either be sold as raw material or left amassed in large piles called tips. A fine slurry waste called mica residue is the other primary waste stream and it is disposed of in large lagoons and abandoned kaolin clay pits (Palumbo-Roe & Colman, 2010). Consequently, kaolin mining can alter physical landscape surfaces, creating environments that are at elevated risk of flooding, runoff, and water erosion events (Duque et al., 2015; Martín-Moreno et al., 2008; Nguyễn et al., 2021; Zapico et al., 2020).

Effects on terrestrial biodiversity

In terrestrial ecosystems, kaolin mining can impact biodiversity at multiple scales, both at the mining site and across regional landscapes (Sonter et al., 2018). However, most research has focused on site-level impacts of habitat loss and environmental degradation. In the northeastern Brazilian Amazon, scientists analyzed the indirect and cumulative effects of kaolin mining at a regional scale (Siqueira-Gay et al., 2022). Within their study area, the researchers found that the cumulative change in forest cover was determined by interactions between kaolin mining, other industrial mining, timber extraction, and agricultural land uses. In this way, kaolin mining contributes to the loss of critical habitat in one of the most diverse ecosystems on earth.

Researchers have studied vegetative succession at kaolin mining sites in southwest England, which hosts the distinctive and diverse Atlantic lowland heath ecosystem (Lane et al., 2020). Dancer et al. (1977) reported that abandoned kaolin mines in the region often hosted a mix of invasive leguminous shrubs, which were better able to tolerate the low nitrogen and poor water-holding capacity of the sandy mining wastes. Although the scientists observed that some sites were subsequently colonized by native woodland species, the characteristic diversity and community structure of the regional heathland did not return. More recently, Lane et al. (2020) studied former kaolin mining sites at varying intervals of restoration (0, 2, 27, and 150 years). They found that even 150 years post-mining, soils were lower in nutrient content and organic matter and higher in pH when compared to undisturbed heathland soils nearby. Additionally, instead of the characteristic heathland shrub species, grasslands predominated at the sites.

Bacteria and fungi found in the soil rhizosphere are critical to soil functions, plant establishment, and nutrient uptake.[6] Gao et al. (2024) studied the rhizosphere bacteria of three native plant species in a Chinese kaolin mine. They found that kaolin mining decreased the abundance, species richness, and functional diversity of these bacteria. Xiao et al. (2024) studied the fungal community for the same plants and sites. The fungal rhizosphere community also differed substantially between mined and unmined sites, with decreased species diversity and functional

[5] *Soil profile* refers to the vertical structure of a soil from the surface down to the bedrock, consisting of distinct layers called horizons that develop over time.

[6] The *rhizosphere* is the region of soil surrounding plant roots, within which the soil chemistry and microbiology are influenced by the interactions between roots and associated soil microorganisms.

diversity and altered species complements in the mined sites compared to the unmined sites. However, the effects differed among the three plant species (Xiao et al., 2024).

In a kaolin mining center in the Czech Republic, saprophytic macromycetes were more abundant and diverse in unmined sites than in kaolin mining sites (Walter et al., 2024).[7] Species known to colonize woody debris were notably absent from recently mined sites, although they were abundant in successional communities at abandoned quarries (Walter et al., 2023). However, parasitic and mycorrhizal fungi, which are better adapted to nutrient-poor soils, were more prevalent in actively mined sites than in unmined or abandoned sites (Walter et al., 2024).

Invertebrates, such as insects and spiders, can be key indicators of ecosystem health. Walter et al. (2023, 2024) studied the abundance and diversity of arthropods at active and abandoned kaolin quarries in the Czech Republic. Among the arthropods that the scientists sampled were 21 species included on the International Union for Conservation of Nature (IUCN) Red List of Threatened Species. The scientists reported that moths and carabid beetles were more abundant and diverse in sites undisturbed by mining. However, active mining sites had a higher diversity of herbaceous plants, attracting more moths that feed on these types of plants. The researchers noted that counterintuitively, mining disturbance creates novel microhabitat islands within a forested landscape, offering secondary refuges for declining or rare species that depend on open habitats like rocky outcrops, grassland, or wetlands (Walter et al., 2023, 2024).

Lastly, megafauna also suffer habitat loss from kaolin mining. Cochran et al. (1999) sampled small mammal and bird communities on successional kaolin mine sites in Georgia. Avian abundance and species richness were highest in the earlier successional sites. However, species that nest and forage in forest interiors appeared only in the older sites. A single species, the cotton rat, dominated the small mammal community on the reclaimed sites. Most of the reclaimed sites hosted a monoculture of loblolly pines, resulting in a uniform, closed canopy. The scientists concluded that these sites lacked the vegetative structure needed to sustain high avian and mammal diversity (Cochran et al., 1999).

Effects on aquatic environments

Open-pit kaolin mining can impact the environment and biodiversity of freshwater ecosystems in several ways. First, surrounding groundwater levels can drop due to the geomorphological changes associated with surface soil and rock removal (Anju & Jaya, 2022). Excavators also heavily alter site topography, affecting drainage networks both above and below ground (Zapico, Laronne, Sánchez Castillo, et al., 2021). Soil erosion and sedimentation around the mine are major risks (Zapico, Laronne, Meixide, et al., 2021; Zapico, Laronne, Sánchez Castillo, et al., 2021). High suspended sediment loads in streams and rivers degrade downstream water quality for both wildlife and human consumption (Gordon & Palmer, 2015; Jordão et al., 2002a; Willhite et al., 2012).

Second, kaolin beneficiation can introduce chemical contaminants to groundwater, surface water, and sediments (Jordão et al., 2002b). Consumers prefer bright, white kaolin. To achieve this, mining companies use large amounts of metallic zinc to chemically remove iron oxides (de Jesus & Sánchez, 2013; Silva et al., 2003). The residual zinc and iron, along with aluminum, cadmium, lead, and other metals are waste products that may contaminate groundwater and surface water (Silva et al., 2003). Mining companies also use sulfuric acid to whiten kaolin (Jordão et al., 2002b, 2002a). Consequently, mine effluents can contain high levels of sulfates and phosphates and can reduce the pH of downstream surface water, as Jordão et al. (2002a, 2002b) detected in Brazil (Jordão et al., 2002a).

Effects on aquatic biodiversity

Previous studies have examined the toxicity of kaolin particles to aquatic species. By analyzing the collated data from these studies, Gordon & Palmer (2015) concluded that suspended kaolin particles are not substantially dangerous to most aquatic organisms. However, most of the species studied were marine organisms. Only one freshwater organism, *Daphnia magna*, was included. This aquatic invertebrate suffered high mortality rates due to ingestion of kaolin particles, which block the animal's gut, resulting in starvation (Robinson et al., 2010). Nevertheless, pure kaolinite proved much less toxic than either pure montmorillonite (a different clay mineral) or a natural clay.

Kaolin appears to be more toxic to larger organisms, both within and between taxa. Salmonids and marine fish larvae are more sensitive to suspended particles than invertebrates (Gordon & Palmer, 2015). Likewise, smaller amphipods were less sensitive to kaolin exposure than larger individuals (Anderson et al., 2015).

[7] *Saprophytic macromycetes* are fungi that produce readily visible, long-lived fruiting bodies and subsist by decomposing biotic materials.

Even if toxicity is low, kaolin mining can alter freshwater aquatic biodiversity. In a kaolin mine impoundment reservoir in Brazil, phytoplankton biomass and zooplankton diversity were substantially reduced compared to similarly sized water bodies that were not impacted by mining (Moreira et al., 2016).

After fully extracting kaolin from an area, mining companies may perform mine reclamation projects to restore the degraded landscape (Duque et al., 2015; Kogel, 2014; Ribeiro et al., 2021). However, ecosystems can take decades to recover after being impacted by mining. In kaolin recovery ponds in Georgia, the diversity and community composition of aquatic algae were related to the time elapsed since mining ceased (Dominy & Manoylov, 2012). The researchers found no algae in a pond sampled two months after mining. Both 2-year and 30-year ponds had diverse algal communities, but community composition differed between the sites. The 30-year pond had significantly higher diversity on average. Further, the particular species that were most predominant differed substantially between sampling dates in the 2-year pond, while the 30-year pond community was much more stable (Dominy & Manoylov, 2012).

We found limited information about the fate and impact of kaolin or kaolin mining wastes that reach marine environments. In 1980, a freighter spilled 2200 tons of kaolin onto a sensitive coral reef in Hawaii (Dollar & Grigg, 1981). Despite concerns of widespread ecological harm, scientists found only minor and localized impact within 50 meters of both sides of the spill site. Within that area, the kaolin smothered some coral, while other detached fragments were alive but slightly bleached. The scientists surmised that, in this case, ocean currents had rapidly removed the kaolin from the area, but they emphasized that every case must be analyzed individually.

Ultimately, while some taxa suffer biodiversity loss as a result of kaolin mining, others may benefit from the establishment of novel ecosystems on disturbed, successional land (Cochran et al., 1999; Jordão et al., 2002a; Salgueiro et al., 2020; Sonter et al., 2018; Walter et al., 2023). Whether the benefits for certain organisms outweigh the harm to others depends on the geographic scale, taxonomic group(s), and ecosystem parameters of interest (Walter et al., 2023, 2024).

Evaluation Question #8: Describe and summarize any reported effects upon human health from use of the petitioned substance [7 U.S.C. 6517(c)(1)(A)(i), 7 U.S.C. 6517(c)(2)(A)(i) and 7 U.S.C. 6518(m)(4)].

Kaolin is Generally Recognized as Safe (GRAS) under 21 CFR 186.1256 [listed as "Clay (kaolin)"] as an indirect food ingredient, provided that it is of a purity suitable for its intended use and limited only by current good manufacturing practice. Specifically, 21 CFR 186.1256(b)(2) states that the GRAS affirmation of kaolin is based on the condition that it is used "in the manufacture of paper and paperboard that contact food." [8] However, there are additional health considerations related to both the production and consumption of kaolin, dependent on the associated use.

Clarification of fruit wines

The Alcohol and Tobacco Tax and Trade Bureau (TTB), rather than the FDA, regulates the treatment of wines and some juice products. According to 27 CFR 24.243, "Inert fibers, pulps, earths, or similar materials, may be used as filtering aids in the cellar treatment and finishing of wine. Agar-agar, carrageenan, cellulose, and diatomaceous earth are commonly employed inert filtering and clarifying aids. In general, there is no limitation on the use of inert materials and no records need be maintained concerning their use." Kaolin is authorized for use to clarify and stabilize wine and juice at § 24.246 [Table 1 to Paragraph (c)], without specific limitation.

Other countries that produce organic fruit wine for import into the U.S. market may have differing requirements (Awe, 2018; Minh, 2022). We found no information concerning the health implications of kaolin use as a processing aid in fruit wine.

[8] However, kaolin might also be GRAS for other uses. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, manufacturers are required to obtain premarket approval for new uses of food additives (Gaynor & Cianci, 2006). Substances that are *Generally Recognized as Safe* (GRAS) for specific uses are excluded from the definition of a food additive under the FD&C Act (Gaynor & Cianci, 2006). As such, GRAS substances do not require premarket approval by the FDA for those specific GRAS uses (Gaynor & Cianci, 2006). Unlike food additive safety determinations, which are made by the FDA, GRAS determinations can be made by non-governmental experts (Gaynor & Cianci, 2006). In 2016, the FDA published an updated Final Rule on GRAS substances, which amended the rule so that the GRAS notification program was voluntary (81 FR 54960-55055, August 17, 2016). The notification program provides a mechanism for a company (or a person) to notify the FDA that a substance is GRAS. However, as the notification is now voluntary, identifying whether a substance is or is not considered GRAS by some experts (such as within food manufacturing businesses) may not always be possible. Furthermore, not all previous GRAS determinations are easily searchable. Therefore, it is possible that there are other uses for kaolin that experts would agree are GRAS.

Ingredients in cosmetic and personal care products

Kaolin is a common ingredient in cosmetics and soaps. In 2023, the Expert Panel for Cosmetic Ingredient Safety concluded that Kaolin is safe for use in cosmetic products under current industry practices and concentrations (Expert Panel for Cosmetic Ingredient Safety, 2023).

Pest control in stored grains

The EPA has established a tolerance exemption for kaolin residues in food when used on or in food commodities to aid in the control of insects, fungi, and bacteria (40 CFR 180.1180; 81 FR 34907) "based on the long history of use of kaolin in food and non-food products with no reported adverse effects" (US EPA, 2021). We found no further information concerning the health implications of kaolin as a pest control.

Paper and paperboard for food-contact packaging

Researchers are continuing to learn about the health implications of using nanokaolin in packaging, sometimes finding contradictory results. Nanokaolin is a type of nanoclay, which could be considered an incidental nanomaterial because it occurs as a byproduct of mechanical homogenization and milling (Ali et al., in press). The European Food Safety Authority (2014) concluded that kaolin particles did not migrate from a multi-layered packaging film. However, recent evidence suggests that nanokaolin particles can leach into food from nanocomposite packaging materials. In one study, nanokaolin filler particles migrated from paperboard into food simulant solutions including water, acetic acid, and aqueous ethanol (Zhang et al., 2020). After comprehensively reviewing the literature, Gmoshinski et al. (2020) recommended that nanoclays be evaluated individually, considering their structure and conditions of use.

Wiemann et al. (2020) studied the effects of kaolin and bentonite nanoparticles on human immune cells and rat lung cells *in vitro* and concluded that kaolinite was relatively less bioactive than bentonite. [9] Kawanishi et al. (2020) evaluated genetic damage to human skin cell lines *in vitro*, finding that finer kaolin particles (median particle size 200 nm) were more damaging than coarser particles (median particle size 4.8 µm). We found no evidence of human clinical studies involving nanokaolin exposure.

Direct ingestion of kaolin

Heavy metals, especially lead and cadmium, are often present in raw kaolin materials, sometimes at levels exceeding what is regarded as safe for consumption (Asowata, 2021; Bonglaisin et al., 2022). Contaminant levels vary widely among kaolin deposits around the world. Heavy metals in raw kaolin clays may pose a particular danger for individuals who practice geophagy, the deliberate consumption of soil-like materials, including clays (Asowata, 2021).

While researchers have detected high levels of toxic elements in geophagic clays (including kaolin), few have studied their metabolism and possible modes of toxicity (Bonglaisin et al., 2022; Gomes, 2018). Reichardt et al. (2009) fed kaolin to rats and reported that digestion of kaolin particles in the intestines, initiated by stomach acids, could allow aluminum to enter the bloodstream. Aluminum is a potential neurotoxin (Reichardt et al., 2009). The researchers also demonstrated that ingested kaolin particles can trigger cellular changes in the intestinal mucosa (Reichardt et al., 2009).

Medical researchers have linked the intentional consumption of kaolin clays to the following health conditions:

- iron-deficiency anemia (Attarha et al., 2021; Bonglaisin et al., 2022)
- anemia during pregnancy (Babah et al., 2024)
- potassium deficiency (Gonzalez et al., 1982; Ukaonu et al., 2003)
- bowel obstruction and perforation (Dokoupil et al., 2019; Grigsby et al., 1999)

Kaolin exposure in mining and processing

Kaolin clays can contain significant amounts of radioactive elements, especially uranium and thorium, and their decay products (Conley, 1978). Kaolin samples from different locations vary considerably in the amounts of radionuclides they contain. Depending on local geology, kaolin mining and processing workers may be exposed to elevated radioactivity compared to average concentrations in soil (see *Table 1*). Manufacturers can remove radioactive material by gravity settling (Conley, 1978). We found no evidence of unsafe levels of radioactivity in commercial kaolin materials.

[9] *In vitro* indicates the study occurs in cells or tissues isolated from the living organism.

Table 1: Mean natural radioactivity of kaolin samples (Bq kg-1)

Location	Sample material	Potassium-40	Uranium series	Thorium series	Reference
Turkey	Kaolin	464	82	95	(Turhan, 2009)
Egypt	Kaolin	31	64	68	(El-Mekawy et al., 2015)
Nigeria	Kaolin deposit	94	38	65	(Adagunodo et al., 2018)
Egypt	Kaolin	21	67	89	(Abd El-Halim, 2019)
Brazil	Raw kaolin clays	358	23	26	(da Silva et al., 2016)
Brazil	Commercial kaolin clays marketed for cosmetics use	449	52	61	(da Silva et al., 2016)
Global mean of natural radionuclide concentration	Soil	400	35	30	(United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), 2000)

Kaolin dust is a respiratory and eye irritant (European Chemical Agency (ECHA), 2023; National Center for Biotechnology Information (NCBI), 2024). Occupational exposure levels for kaolin are presently regulated by OSHA at 29 CFR 1910.1000 Table Z-1 (see Table 2). Chronic exposure can cause pulmonary fibrosis or pneumoconiosis (International Programme on Chemical Safety (IPCS), 2005; Wiemann et al., 2020). Kato et al. (2017) demonstrated that kaolin particles can also damage the DNA of cells lining the lungs of mice *in vivo.* [10] Researchers have extensively studied pulmonary disease, also called kaolinosis, in kaolin workers in the United Kingdom and the Southeastern United States. However, quartz, present in the raw kaolin clay, is at least an order of magnitude more potent than refined kaolin (International Programme on Chemical Safety (IPCS), 2005). Kaolin mining and production workers were exposed to considerable amounts of airborne dust before the 1960s, but improved wet processing methods (see *Background*, above) and ventilation systems have substantially reduced exposure (International Programme on Chemical Safety (IPCS), 2005).

Table 2: Kaolin occupational exposure limits

Regulatory Body	Total dust (Time-weighted average)	Respiratory fraction (Time-weighted average)	Reference
NIOSH REL	10 mg/m^3	5 mg/m^3	(OSHA, 2021)
OSHA PEL	15 mg/m^3	5 mg/m^3	(OSHA, 2021)
CAL/OSHA PEL	Not listed	2 mg/m^3	(OSHA, 2021)
EC OEL	Not listed	2 mg/m^3	(INCHEM, 2016)

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[10] *In vivo* indicates the study occurs within the living organism.

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