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TITANIUM DIOXIDE

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I. Summary

Titanium dioxide (TiO₂) (CAS number 13463-67-7, INS 171, molecular weight 79.87) is a white insoluble crystalline powder with a high refractive index. It is used as a colour in various food categories to make food visually appealing and/or to restore the original appearance of food. In the European Union (EU), the food additive E171 refers to food-grade TiO₂. INS 171 and E171 are equivalent except that INS 171 does not include the TiO₂ coating of pearlescent pigments (INS 176).

TiO₂ is widely used as a white pigment in products such as paints, coatings, plastics, paper, inks, fibres, and food and cosmetics because of its brightness and high refractive index (> 2.4), which determines the degree of opacity that a material confers to the host matrix. The high refractive index, surpassed by few other substances, allows TiO₂ to be used at relatively low levels to achieve its technical effect. Various grades of TiO₂ are used in many applications and can also be found in personal healthcare products such as toothpaste and pharmaceutical tablets (Bischoff *et al.* 2021).

TiO₂ may occur as one of several crystal structures; anatase, rutile or a mixture of these crystal forms are used in foods. Commercial food-grade TiO₂ is produced from titanium-containing ores by either the sulfate or chloride process. In the sulfate process, sulfuric acid is used to digest ilmenite (FeTiO₃) or ilmenite and titanium slag. Purification steps include removal of the iron sulfate and crystallization of the TiO₂. Anatase or rutile are formed based on the process used to induce crystallization. The isolated TiO₂ is washed with water, calcined, and milled to a powder. In the chloride process, titanium-containing ore is reacted either with chlorine gas or concentrated hydrochloric acid to form titanium tetrachloride which is then oxidized or hydrolysed at high temperature to produce TiO₂, which is then filtered, washed, and calcined. The chloride process results in TiO₂ in the rutile form. Food-grade TiO₂ is produced without any coating.

The majority of food-grade TiO₂ is produced by the sulfate process in the anatase crystal structure. The functional effect of TiO₂ is attributed to particles (including aggregates and agglomerates) with sizes that range between 200 nm and 300 nm. TiO₂ particles less than 100 nm in diameter are transparent to visible light and are not of functional significance in food. Small TiO₂ particles have a greater tendency to agglomerate and/or aggregate than large particles (Parrino and Palmisano 2020). The reported particle size distribution of food-grade TiO₂ is broad with samples shown to contain particles that range approximately from 30 nm to 400 nm.

Uses of TiO₂ as a food additive are broad. The United States of America regulations authorize its use as a colour additive at levels not to exceed 1% in foods in general. India restricts use of TiO₂ to chewing gum and bubble gum at levels not to exceed 1%, and to powdered concentrate mixes

for fruit beverage drinks not to exceed 100 mg/kg. Japan lists use of TiO₂ as a food colour without limitation in specific food categories. TiO₂ (E171) is no longer used in foods in the European Union [Commission Regulation (EU) 2022/63].

2. Description

Titanium dioxide or titanium (IV) oxide (TiO₂, molecular weight 79.87).

CAS No. 13463-67-7.

Synonyms: INS 171, Titania

TiO₂ can be found in nature as a component of several minerals including ilmenite, rutile, anatase, and leucosene. It can be made as one of the following crystal structures: rutile, brookite, and anatase. The titanium dioxide-rich minerals do not appear white, because of the presence of impurities, such as iron, chromium, or vanadium. Anatase and rutile are the two commonly used crystal structures for food-grade applications (Braun, 1997). Rutile is the thermodynamically stable crystal structure of TiO₂; anatase rapidly transforms to rutile above 700 °C. Rutile melts between 1830 °C and 1850 °C (Kirk-Othmer, 1997; Kirk-Othmer, 2006).

Commercial TiO₂ is marketed as a white to slightly coloured powder. Most TiO₂ in the anatase form is produced as a white powder, whereas various rutile grades are often off-white and can even exhibit a colour, depending on the physical form, which affects light reflectance. TiO₂ may be coated with small amounts of alumina and silica to improve technological properties, however, coated TiO₂ is not an article of commerce for use in food.

TiO₂ is insoluble in water, hydrochloric acid, dilute sulfuric acid, and organic solvents. It dissolves slowly in hydrofluoric acid and hot concentrated sulfuric acid. It is almost insoluble in aqueous alkaline media (Kirk-Othmer, 1997).

3. Method of manufacture

Commercial TiO₂ pigment is produced by either the sulfate process or the chloride process. The principal raw materials for manufacturing TiO₂ include ilmenite (FeO/TiO₂), naturally occurring rutile ore, and titanium slag.

Sulfate Process (Kirk-Othmer, 1997; Kirk-Othmer, 2006; DeMerlis, 2005)

Both anatase and rutile grades of TiO₂ can be produced by the sulfate process. Briefly, ilmenite or ilmenite and titanium slag is digested with sulfuric acid and the product is diluted with water or dilute acid. Most of the TiO₂ from the ore is solubilized as titanium oxo-sulfate and iron is present in its +II oxidation state. The resulting liquor is clarified by sedimentation to remove insoluble residues such as silica. Iron is removed by crystallization as its sulfate salt (FeSO₄•7H₂O), followed by filtration.

To produce the anatase crystal form of TiO₂, a small portion of the clarified liquor is neutralized with alkali to produce anatase microcrystals. These microcrystals are then introduced into the mother liquor, which is then hydrolysed under carefully controlled conditions to produce crystals of anatase. These are subsequently filtered, washed, calcined, and milled to a powder. During calcination, the final temperature reaches about 800 °C-850 °C.

To produce the rutile crystal form of TiO₂, the clarified liquor is hydrolysed in the presence of a specially prepared rutile seeding agent obtained by neutralizing a small portion of the mother

liquor in the presence of hydrochloric acid or some other monohydric acid. Formed crystals are filtered, washed, and calcined at temperatures between 900 °C and 930 °C, and milled to a powder.

Chloride Process (Kirk-Othmer, 1997; Kirk-Othmer, 2006; DeMerlis, 2005)

The chloride process yields the rutile form of TiO₂. Chlorine gas is reacted in a fluidized bed reactor with a titanium-containing mineral, e.g. mineral rutile, under reducing conditions (presence of coke) and at temperatures between 800 °C and 1200 °C, to form anhydrous titanium (IV) chloride. Purification of the anhydrous titanium (IV) chloride requires separation by fractional condensation. Conversion of titanium (IV) chloride to TiO₂ may be accomplished by either direct thermal oxidation or reaction with steam in the vapour phase at temperatures in the range of 900 °C-1400 °C. A minor amount of aluminium chloride is generally added to promote formation of the rutile form. The TiO₂ is washed, calcined, and packaged.

Alternatively, the titanium-containing mineral can be reacted with concentrated hydrochloric acid to form solutions of titanium (IV) chloride which are then further purified. Hydrolysis of titanium (IV) chloride will yield TiO₂ which is filtered, washed, calcined, and packaged (DeMerlis, 2005).

Based on recent publications and data available to the Committee, the predominant form of TiO₂ used in food is anatase. This implies that the relevant manufacturing process for the production of TiO₂ for use in food is the sulfate process. In addition, TiO₂ used in food is produced without any coating.

Other Processes

TiO₂ is also manufactured for non-food applications using methods that differ from the sulfate and chloride processes; these include sol-gel, microemulsion, precipitation, hydrothermal, solvothermal, electrochemical, and enzymatic methods. These methods utilize different precursors, additives, and size control agents, which result in TiO₂ particles with specific sizes, narrow size distributions, and unique geometries. TiO₂ obtained from such manufacturing processes are not geared towards food additive use. The subject of this evaluation is food-grade TiO₂ as defined by INS 171.

4. Characterization

4.1. Composition

TiO₂ can be prepared at a high level of purity. Specifications for food use currently contain a minimum purity assay of 99.0% (Food Chemical Codex (FCC), 2008; Japan, 2018; JECFA, 2023). Maximum limits for Loss on Drying (Japan, 2018; JECFA, 2023) and Loss on Ignition (FCC, 2008; Japan, 2018; JECFA, 2023) have also been established.

4.2. Possible Impurities

The possible impurities in TiO₂ arise from the impurities in the ores and solvents used in the manufacturing process. Table 1 indicates the maximum limits specified by JECFA, FCC, Japan and U.S. Food and Drug Administration (FDA) specifications listed in the regulation for various impurities in TiO₂.

Table 1: Maximum Specified Limits for Impurities in TiO₂ *

Impurity	JECFA (2023)	FCC (2008)	Japan (2018)	FDA (21 CFR 73.575)
Acid-soluble substances	Not more than 0.5%	Not more than 0.5%	Not more than 0.50%	Not more than 0.5%
Water-soluble matter	Not more than 0.5%	Not more than 0.3%	Not more than 0.25%	Not more than 0.3%
Antimony	Not more than 2 mg/kg	Not more than 2 mg/kg	–	Not more than 2 mg/kg
Arsenic	Not more than 1 mg/kg	Not more than 1 mg/kg	Not more than 1 mg/kg	Not more than 1 mg/kg
Cadmium	Not more than 0.5 mg/kg	–	–	–
Lead	Not more than 5 mg/kg	Not more than 10 mg/kg	Not more than 10 mg/kg	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg	Not more than 1 mg/kg	–	Not more than 1 mg/kg

*Specifications for silicon dioxide and aluminum dioxide content in TiO₂ are omitted.

4.3. Particle Size and Particle Size Distribution of TiO₂

4.3.1. Use of Electron Microscopy (EM) Methods

The functional effect of TiO₂ is attributed to particles (including aggregates and agglomerates) with size that ranges between 200 nm and 300 nm. TiO₂ particles less than 100 nm are transparent to visible light and are not of functional significance in food. Small TiO₂ particles have a greater tendency to agglomerate and/or aggregate than large particles (Parrino and Palmisano, 2020).

The particle size and particle size distribution of the TiO₂ used in food have been reported by academic research groups, industry, and regulatory authorities. The reported particle size of food-grade TiO₂ vary depending on the sample preparation and analysis method, whereas the particle size distribution covers a range from approximately 30 nm to 400 nm. Methods used to measure particle size and size distribution include transmission electron microscopy (TEM), scanning electron microscopy (SEM), dynamic light scattering (DLS), disc centrifugation (DC), asymmetric field flow fractionation coupled with inductively coupled plasma mass spectrometry (AF4-ICPMS), and single particle ICP-MS (sp-ICPMS) (OECD, 2023 and Hodoroaba, 2020).

TEM and SEM are most suitable for the measurement of constituent particles (smallest unit of aggregates or agglomerates). Verleysen *et al.* (2020) determined particle size and particle size distribution by TEM in nine food-grade TiO₂ samples; these samples were purchased from webshops that specialized in bakery and confectionery products from several countries within the European Union. They found a significant variation in the particle size (i.e. Feret diameter of 79 nm-182 nm) with 18-70% (by number) of the measured constituent particles being <100 nm. Yang *et al.* (2014) measured particle size by TEM for five TiO₂ samples identified as food-grade from two different vendors. Four of these samples were purchased from Chinese vendors that ship to the US and/or Europe and one from a commercial supplier in Italy. The authors reported particle size ranging from 106 nm to 132 nm with at least 17% <100 nm particles (by number). Geiss *et al.* (2020) determined also by TEM the mean particle size in five pristine E171 samples to be in the range of 82.9 nm-139 nm, and the fraction of particles < 100 nm to be 23.6-49.3% (by number). Dudefoi *et al.* (2017) used TEM to analyse seven pristine E171 samples from three different suppliers and manufacturers respectively, both from Europe; they determined the mean

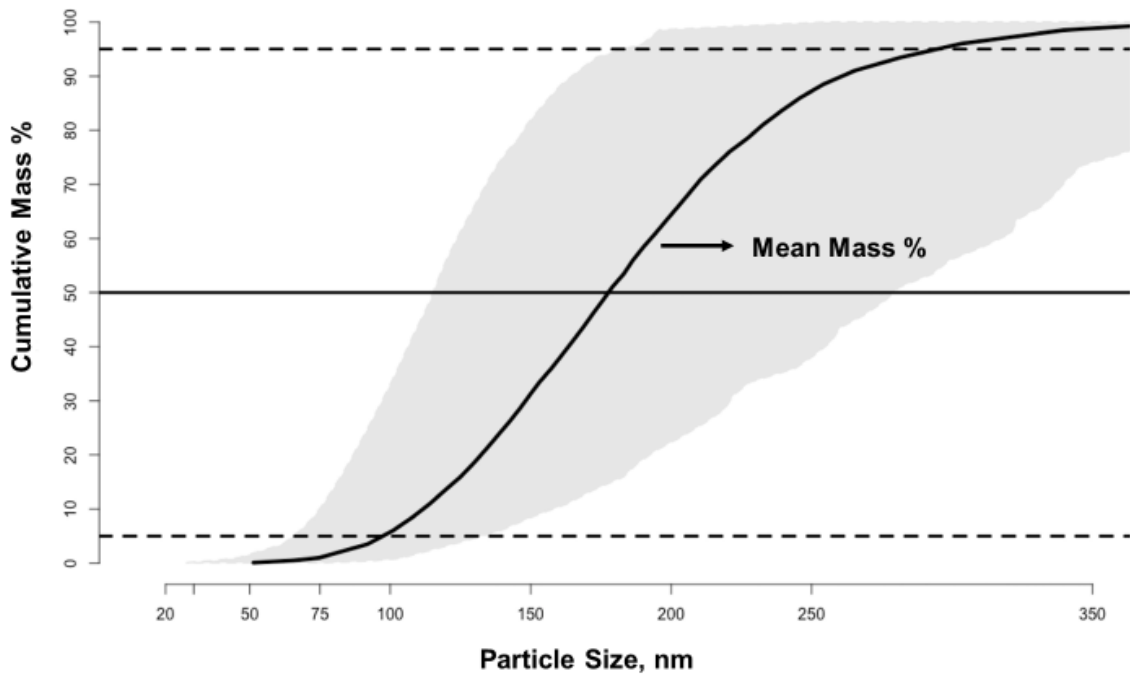
particle size of these samples to be in the range of 115 nm to 145 nm, and the fraction of particles < 100 nm to be 17-36% (by number).

Several studies have reported results for SEM analyses of TiO₂ that is used in food, including that by EFSA (2019), which reported SEM results for the mean particle size of five commercial E171 samples to be between 104 nm to 166 nm and the fraction of particles <100 nm to be in the range of 18.4-45.6% (by number). Peters *et al.* (2014) used SEM to determine the particle size of seven pristine TiO₂ samples; the authors found the apex to be between 200 nm-400 nm and with a fraction of particles <100 nm to be 10% (by number). Hwang *et al.* (2019) measured the average particle size of five TiO₂ samples using SEM to be 118 nm-169 nm, with 22% of the particles (by number) <100 nm.

Variation in the average particle sizes of the samples analysed by either TEM or SEM can be attributed to several factors, including differences in the sample preparation, lack of reference materials, and differences in processing the raw data. The available reference materials that most studies used are of particle size <100 nm (e.g. P25) (Dudefoi *et al.*, 2017), with narrow size distribution, and are not relevant to TiO₂ used as a food additive. Typically, TiO₂ dispersions are subjected to sonication for 5 to 30 minutes. However, the details of the sonication conditions, such as sonication power, frequency, and type of set-up (probe or bath), are missing from the sample preparation protocol of some studies. These parameters are crucial because they can affect the measurements of particle size and size distribution. For instance, the median particle size (D50) for the E171 samples measured by Verleysen *et al.* (2020), which utilized probe sonication with a power 35 kJ, is lower (i.e. 89 nm) than a case when sample preparation step did not utilize sonication (i.e. 97 nm). Furthermore, processing of the raw data can introduce additional variability because of the variation in measurement parameters such as particle selection for a given image, the total number of particles analyzed, and measurement technique (manual versus using the aid of a software).

Current analytical results from selected laboratories indicate acceptable within-lab precision whereas the reproducibility between individual laboratories is widely divergent (Figure 1). An internationally agreed upon method for determination of particle size distribution that has been standardized and validated through collaborative testing is not currently available for the determination of particle size distribution in the article of commerce. Such a method must include suitable preparation steps such that the test article retains the size and surface chemistry properties. Similarly, there are no harmonized methods available for the extraction and characterization of TiO₂ particles in food matrices. Despite the uncertainty in the determination of particle size distribution, based on the current state of the art, particles smaller than 30 nm, if present, are only expected to be at trace levels. As shown in Figure 1, even though the reported cumulative mass distribution per particle size varies within the grey area, the % mass that is in particles below 30 nm converges to zero.

Figure 1: Intra-lab variability of particle size measurement of TiO₂ samples representative of INS 171 using TEM, converted to cumulative mass % distribution of particles; the grey area indicates the extent of particle size distributions. Observed inter-lab variability was larger than between-sample variability, for data from the same laboratory. A mean curve is also shown as a black solid line.



4.3.2. Use of Alternative Analytical Methods

Alternative analytical methods have been reported to analyse the particle size and size distribution of TiO₂. However, these methods may not be able to distinguish between constituent particles from aggregates and agglomerates. Nevertheless, they can complement the EM methods in terms of particle size distribution in dispersion. For instance, Geiss *et al.* (2020) determined the particle size of pristine TiO₂ samples and the fraction of particles <100 nm using single particle Inductively Coupled Plasma Mass Spectrometry (sp-ICPMS) to be 170 nm-220 nm and 11%-18.8%, respectively. Using a higher power of probe sonication compared to that used by Geiss *et al.* (2020), Verleysen *et al.* (2020) determined the particle size of pristine TiO₂ samples and its fraction of particles <100 nm using sp-ICPMS to be 83 nm-125 nm and 32%-64% (by mass), respectively.

An interlaboratory comparison study was conducted to test the transferability of the sp-ICPMS among seven experienced European food control and food research laboratories equipped with various ICPMS instruments and using different software packages (Geiss *et al.*, 2021). As a confirmatory technique and to serve as the basis for bias estimation, the laboratories used TEM. For TiO₂ samples in relatively simple food matrices, bath sonication proved to be sufficient to reach the highest achievable degree of dispersed constituent particles. On the other hand, for pristine TiO₂, probe sonication was required. When compared to TEM results, the mean and median particle sizes that were measured using sp-ICPMS are higher. This may be due to the higher size detection limit for sp-ICPMS and/or the presence of agglomerated and/or aggregated particles even after sonication.

Dynamic Light Scattering (DLS) can also be used to determine the hydrodynamic diameter of TiO₂ in an aqueous dispersion. These hydrodynamic diameters are expected to be larger than the size measured using EM methods since DLS takes into account the solvation layer of the particles. The particles detected by DLS are typically aggregated and agglomerated. For instance, Yang *et al.* (2014) measured the Z-average hydrodynamic diameter of sonicated aqueous dispersions of pristine TiO₂ to be 127 nm-504 nm. Hwang *et al.* (2019) measured the Z-average hydrodynamic diameter of sonicated aqueous dispersions of pristine TiO₂ to be 285.30 nm-345.27 nm.

Less common methods that incorporate the separation of particles prior to their detection have

also been used to analyse the particle size and size distribution of TiO₂. Although these techniques may offer more resolution across different particle sizes, the conversion from volume to number distributions introduces inherent errors in the measurements. Nevertheless, these methods have been shown to complement other techniques described above. For example, Peters *et al.* (2014) used Asymmetric Flow Field Flow Fractionation (AF4) coupled to ICPMS (AF4-ICPMS) to analyse non-sonicated dispersion of pristine TiO₂ and found that the apex of the size distribution is between 200 nm and 300 nm. In addition, the fraction of particles < 100 nm is 10%-15%, which is consistent with what was observed using EM analysis. Geiss *et al.* (2020) determined that the pristine TiO₂ samples had a particle size distribution between 100 nm and 400 nm, based on absorbance-based size distribution using disc centrifugation (DC) with laser detection. However, transformation from absorbance-based to mass-based and number-based particle size distributions proved challenging as significant irreproducible artifacts were generated. EFSA (2019) reported results from business operators using DC with X-ray detection and laser detection, showing a range of median volume-based particle size between 260 nm and 380 nm and the fraction of particles < 100 nm (by volume) to be 0%-1.52%.

4.3.3 Recommendations for the Characterization of TiO₂ (INS 171)

1. Studies should be performed using fully traceable samples of the article of commerce.
2. Studies should be performed to characterize the article of commerce using a variety of fully validated techniques to determine physical and chemical properties including particle size, size distribution, zeta potential, specific surface area, photoactivity, isoelectric point and surface elemental composition. Techniques such as SEM, TEM, DLS, XPS, sp-ICPMS and laser diffraction may be employed (Hodoroaba *et al.*, 2020).
3. Sampling and sample preparation are critical. Protocols should therefore include detailed instructions on sampling and sample preparations, harmonized internationally and collaboratively tested (OECD, 2023).
4. The same types of data and harmonized protocols (as indicated in points 2 and 3) should be generated for TiO₂ as it exists in the allowed range of food matrices, with particular caution given to the treatment of the food and the extraction of TiO₂ such that the particle size and surface characteristics are not altered.
5. Well characterized reference materials should be developed for both the food additive and incurred food matrices.
6. In all cases, data processing should be clearly defined, and preference given to results presented on a mass basis rather than solely on particle number.

5. Functional uses in Food

TiO₂ is highly effective as a whitener for confectionary, baked goods, cheeses, icings, toppings, and food supplements. When combined with other colours, soft pastel shades can be achieved. As TiO₂ is not water-soluble, applications require dispersion using vehicles such as food oils, propylene glycol, sugar syrup, or water with select thickeners (Gerdes, 2004; Vaughn, 2006).

The United States FDA has authorized the use of TiO₂ in foods, in general, at a limit not to exceed 1% by weight of the food. Silicon dioxide and aluminium oxide may be used with the TiO₂ as “dispersing aids” at levels not to exceed 2% by weight, singly or in combination, of the TiO₂ (21 CFR 73.575).

TiO₂ is no longer used in foods in the European Union. As part of EFSA’s reassessment of TiO₂ for use as a food additive, they reported the use levels of TiO₂ in various food categories prior to the 2022 ban, including flavoured fermented milk products including heat-treated products, dairy

analogues, edible ices, other confectionery including breath-refreshening microsweets, chewing gum; certain decorations, coatings and fillings; fine bakery wares; soups and broths; sauces; salads and savoury-based sandwich spreads; certain protein products, certain flavored drinks; processed nuts; certain desserts; and certain food supplements in solid and liquid forms. The concentration of TiO₂ from these food categories ranges from 39 mg/kg in flavoured drinks to 14,438 mg/kg in certain dietary supplements (EFSA, 2021).

India restricts the uses of TiO₂ to chewing gum and bubble gum with a level not to exceed 1% and to powdered concentrate mixes for fruit beverage drinks not to exceed 100 mg/kg (India, 2011).

Japan lists its use as a food colour without limitation, other than specifying certain foods (e.g. fish pickles, fresh fish/shellfish, kasutera, kinako, konbu/wakame, legumes, wakame, etc.) in which it is not permitted (Japan, 2018).

6. Reactions and fate in foods

Given its insolubility in water, hydrochloric acid, dilute sulfuric acid, and organic solvents, TiO₂ is not expected to react with components of food. Its functionality depends upon its inertness within a food matrix. In fact, The JECFA Committee at its 13th meeting (JECFA, 1970) “decided not to establish a limit on intake of TiO₂ since the evidence indicates that it is free from toxic effects on account of its insolubility and inertness. The intake in food would be limited by good manufacturing practice.”

Depending on the environment to which TiO₂ is exposed, certain properties of TiO₂ may change, including its zeta potential, surface chemistry, and aggregation/agglomeration state. For instance, the zeta potential of TiO₂ particles in aqueous dispersion varies depending on the pH (Verleysen, 2020). The isoelectric point (IEP) of TiO₂ is between 3 and 4, and dispersions with more negative zeta potentials, typically between pH 6 and 11, exhibit stable dispersions. However, the presence of certain salts and proteins does not alter the properties of TiO₂. For example, TiO₂ food additive in 0.75% bovine serum albumin (BSA), 2 mM sodium bicarbonate (with and without organic carbon), and sodium chloride (up to 5,000 mg/L) solutions resulted in particle diameter of the aggregates/agglomerates (as determined using DLS) similar to the size of the aggregates/agglomerates of pristine TiO₂ food additive (Weir *et al.*, 2012).

The presence of various components of food may affect the properties of TiO₂ particles in food matrices. For instance, using a novel method for harvesting TiO₂ with positively charged magnetic particles, Luo *et al.* (2022) found that the size of the TiO₂ food additive isolated from candy and jelly samples tend to be on the lower end of the range as compared to that of the TiO₂ food additive isolated from chocolate and gum samples. They attributed the discrepancy to the presence of an organic acid, particularly citric acid in candy and jelly samples. They investigated the mechanism of the transformation of the size of TiO₂ food additive in candy and jelly samples using simulated food in the form of TiO₂ combined with melted sugar and various acids (ascorbic acid, acetic acid, and citric acid) at different temperatures and concluded that regardless of temperature, the presence of high concentration of citric acid (~10%) could potentially dissolve TiO₂ on the surface of the particles, leading to the reduction of particle size and fragmentation. Hwang *et al.* (2019) isolated TiO₂ by digestion of the samples with nitric acid and hydrogen peroxide, from various commercial food products, such as candy, chocolate, chewing gum, jelly, sauces, and snacks, as well as from simulated food (e.g. a mixture of ground sugar and TiO₂) for further characterization. They reported the zeta potential of TiO₂ food additive isolated from some food samples indicates less negatively charged. However, the SEM and DLS analyses of the TiO₂ food additive isolated

from the food samples indicate that the morphology, size distribution and aggregation and/or agglomeration state of the TiO₂ particles are similar to those of a pristine TiO₂ sample.

Although there is lack of extensive studies investigating the effect of food matrices on the physicochemical properties of TiO₂ food additive, the available studies indicate that the agglomeration/aggregation state of the TiO₂ particles in food are generally comparable to that in pristine TiO₂. Some food components may have an effect on the constituent particle size; however, further investigation is needed to ascertain the relevance of this effect to more complex food matrices. Additionally, the zeta potential of the TiO₂ particles in food may vary depending on several factors including pH and components of food.

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