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Safety assessment of the substance, titanium dioxide surface treated with fluoride-modified alumina, for use in food contact materials

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Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) is a safety assessment of the additive titanium dioxide surface treated with fluoride-modified alumina, a defined mixture of particles of which [redacted]% in number have a diameter in the range of 1–100 nm. It is intended to be used as filler and colourant up to 25% w/w in potentially all polymer types. Materials and articles containing the additive are intended to be in contact with all food types for any time and temperature conditions. The data provided demonstrate that the additive particles stay embedded even in swollen polar polymers such as polyamide, and do not migrate. Moreover, the additive particles resisted release by abrasion and did not transfer into a simulant for solid/dry foods. Thus, the additive particles do not give rise to exposure via food and to toxicological concern. Migration of solubilised ionic fluoride and aluminium occurs from the surface of the additive particles and particularly from swollen plastic. The Panel concluded that the substance does not raise safety concern for the consumer if used as an additive up to 25% w/w in polymers in contact with all food types for any time and temperature conditions. However, uses in polar polymers swelling in contact with foodstuffs simulated by 3% acetic acid should be limited to conditions simulated by contact up to 4 h at 100°C. This is due to the fact that when used at 25%, and contact was followed by 10 days at 60°C, the migration of aluminium and fluoride largely exceeded the specific migration limit (SML) of 1 and 0.15 mg/kg food, respectively. The Panel emphasises that the existing SMLs for aluminium and fluoride should not be exceeded in any case.

Keywords: titanium dioxide surface treated with fluoride-modified alumina, nano, FCM substance No. 1077, food contact materials, safety assessment, evaluation

Requestor: Food Standards Agency, United Kingdom

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Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The following information has been provided under confidentiality and it is redacted awaiting the decision of the Commission: the manufacture of the substance, in particular the identity of certain chemicals used in the process; the characterisation of the substance, in particular the proportion of fluoride, the fraction of particles below 100 nm, the range of particles number above 100 nm; the illustration of the structure formed; and the fraction of particles below 100 nm once incorporated in the plastic.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list, EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004[1] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States competent authorities which transmit the applications to the European Food Safety Authority (EFSA) for their evaluation.

In this case, EFSA received an application from the Food Standards Agency, United Kingdom, requesting the evaluation of the substance titanium dioxide treated with fluoride-modified alumina with the FCM substance No 1077. The dossier was submitted on behalf of DuPont Titanium technologies, currently the Chemours Company.

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of its application for the authorisation of the substance titanium dioxide treated with fluoride-modified alumina, to be used in plastic food contact materials.

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 16 July 2015, 22 January 2016, 18 December 2017 and 16 April 2019 (see 'Documentation provided to EFSA').

Data submitted and used for the evaluation are:

Non-toxicological data

- Data on identity and characterisation of the particles
- Data on physical and chemical properties
- Data on intended use and authorisation
- Data on residual content of the substance
- Data on migration of the substance, aluminium, titanium and fluoride
- Data on the surface analysis and the swelling of polyamide 66
- Data on possible release due to abrasion.

Toxicological data

- None.

2.2. Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines.

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from

[1] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently, there are three tiers with different thresholds triggering the need for more toxicological information as follows:

a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA 'Guidance on transparency in the scientific aspects of risk assessment' (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee such as the 'Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' (EFSA Scientific Committee, 2018).

3. Assessment

According to the applicant, the additive named 'titanium dioxide treated with fluoride-modified alumina', renamed by the CEP Panel 'titanium dioxide surface treated with fluoride-modified alumina', is a defined mixture of particles, of which [redacted]% in number have a diameter in the range of 1–100 nm. It is intended to be used as filler and colourant up to 25% w/w in potentially all polymer types. According to the applicant, it aims to reduce discoloration of resin compounds and finished plastic articles during processing and exposure to ultraviolet light. Materials and articles are intended to be in contact with all food types for any time and temperature conditions.

The substance was not evaluated by SCF and EFSA in the past. However, titanium dioxide (TiO_2) was evaluated by the SCF in 1975 and is authorised/listed in Regulation (EU) No 10/2011[2] under the FCM number No 610 without a specific restriction. It was also evaluated by the EFSA ANS Panel in 2016 and 2018 for its uses as food additive (EFSA ANS Panel, 2016, 2018), and it is authorised in both anatase and rutile forms for certain types of food (E 171) in the Regulation (EC) No 1333/2008 on food additives.[3] In its evaluation in 2016, '…The Panel considered that, on the database currently available and the considerations on the absorption of TiO2, the margins of safety (MoS) calculated from the NOAEL of 2,250 mg TiO2/kg bw per day identified in the toxicological data available and exposure data obtained from the reported use/analytical levels of TiO2 (E171) would not be of concern'.

Regulation (EU) No 2016/1416 of 24 August 2016, amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food[4] established a specific migration limit (SML) for aluminium of 1 mg/kg food or food simulant that applies since 14 September 2018.

Some fluoride-containing substances are authorised and listed in the Regulation (EU) No 10/2011, among which the substance silicic acid, magnesium-sodium-fluoride salt (FCM number 685) has a SML of 0.15 mg/kg food or food simulant, expressed as fluoride.

3.1. Non-toxicological data

The purity of titanium dioxide surface treated with fluoride-modified alumina is above 99.9% based on the analysis of inorganic impurities. The proportions of titanium dioxide, aluminium oxide (as Al_2O_3) and fluoride are declared to be ≥ 94.5%, 2.4–3.2% and [redacted]%, respectively. The substance is insoluble in water and octanol, and slightly soluble in acidic simulants. Its density is in the range of 3.8–4.4 g/cm^3. It is made by reacting titanium dioxide with [redacted] and alumina. The substance cannot be represented by a discrete chemical structure.

[2] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1.

[3] Regulation (EC) No. 1333/2008 of the European parliament and of the council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[4] Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. OJ L230, 25.8.2016, p. 30.

Example of the formed structure:

[redacted]

The crystalline form of the titanium dioxide core, rutile and/or anatase, is not specified. The additive has a 'tail' of nanosized particles. The particle size distribution was characterised by transmission electron microscopy (TEM) and by an X-ray disk centrifuge. The TEM analysis indicates that on particle-number basis ca. [redacted]% have a minimum Feret diameter in the range of 1–100 nm, the rest being in the range of [redacted]. The X-ray disk centrifuge indicates that 50% have a hydrodynamic diameter of [redacted]. Using TEM, the additive was also characterised once incorporated at the maximum intended use of 25% w/w into low-density polyethylene (LDPE) and polyamide 66. The number of particles with a diameter below 100 nm slightly increased. The increase was attributed to a slight bias towards agglomeration of larger particles in the polymers meaning that the smaller particles reach a slightly higher numerical percentage.

Considering its nature, the substance is not expected to give rise to new organic substances with potential to migrate from plastics. Therefore, the assessment focused on potential migration of the inorganic additive itself in particulate or ionic forms.

Potential migration of the substance (at the maximum intended use level of 25% w/w) was investigated by means of (i) theoretical considerations based on migration modelling, (ii) specific migration from LDPE (non-polar) and polyamide 66 (polar) materials, (iii) surface analysis of the polyamide 66 before and after exposure to 3% acetic acid, (iv) specific migration from polyamide 66 using a surfactant solution as an alternative food simulant and (v) an abrasion test of LDPE.

i) Theoretical considerations

The potential migration of the substance in particulate form was investigated using theoretical considerations based on diffusion models. Under conservative assumptions (e.g. high solubility in food simulants, small particles/effective molecular masses), the modelling estimated migration to be below 0.1 μg/kg food. This modelling does not cover situations where a strong interaction with food/simulant can give rise to polymer swelling.

ii) Specific migration from LDPE (non-polar) and polyamide 66 (polar) materials

Specific migration of aluminium, titanium and fluoride was determined from LDPE plaques into 3% acetic acid as well as 10% and 95% ethanol. Test conditions were 4 h at 100°C, followed by 10 days at 60°C using 3% acetic and 10% ethanol, and 4 days at 60°C, followed by 10 days at 60°C using 95% ethanol. The surface to volume ratio was approximately 6 dm^2/L. In 3% acetic acid, titanium was not detected at the limit of detection (LoD) of 5 μg/kg food simulant, whereas fluoride and aluminium were measured at 50 and 66 μg/kg simulant, respectively. Migration into the water-ethanol simulants were below that into 3% acetic acid (limited data due to analytical method limitations).

Migration may be higher from polar polymers (e.g. polyamides, polylactic acid) combined with aqueous foods and food simulants (such as water and 3% acetic acid), which is due to interactions with the polymers, including swelling. Therefore, migration of aluminium and titanium was determined from polyamide 66 plaques into 3% acetic acid. Test conditions were 4 h at 100°C (to simulate short-term heating) and 4 h at 100°C, followed by 10 days at 60°C (to simulate short-term heating plus long-term storage). The surface to volume ratio was approximately 6 dm^2/L. Swelling was determined after contact for 4 h at 100°C, followed by 10 days at 60°C and then 31 days equilibration at room temperature. Mass uptake was 3.4% and the thickness of the polyamide plaques increased by 1.9%. The same swelling effect was seen for a polyamide control sample without the additive incorporated. Migration of aluminium was 0.54 mg/kg after 4 h at 100°C and increased to 4.7 mg/kg when followed by 10 days at 60°C. Using inductively coupled plasma mass spectroscopy (ICP-MS), migration of titanium after 4 h at 100°C followed by 10 days at 60°C was 5 μg/kg. Fluoride was not measured in these experiments. Assuming the same ratio of aluminium:fluoride as seen for the migration from LDPE, migration of fluoride could be estimated at about 0.4 mg/kg after 4 h at 100°C and about 3.6 mg/kg when followed by 10 days at 60°C.

Due to the swelling of polyamide 66 in contact with 3% acetic acid and the measured migration of titanium and aluminium, the simulant obtained after 4 h at 100°C followed by 10 days at 60°C was analysed by centrifugal ultrafiltration with a 10-kDa membrane, said to retain particles above 1–2 nm. The concentrations of aluminium and titanium before ultrafiltration and in the filtrate were the same within the precision of the test method (RSD of ca. 1%), indicating that the aluminium and titanium in the simulant were 'sized' below 1–2 nm – in fact most likely in dissolved, ionic form. It was noted, however, that the stability and recovery of additive particles in/from the simulant as well as the exact cut-off performance of the membrane used, were not checked.

iii) Surface analysis of the polyamide 66

The surface of the polyamide 66 (made with the maximum intended use level of 25% w/w) was analysed by scanning electron microscopy (SEM) before and after exposures to 3% acetic acid (after 4 h at 100°C and after 4 h at 100°C followed by 10 days at 60°C). No changes in the size or distribution of particles were observed on the surface microstructure. Energy dispersive spectroscopy (EDS) showed that the titanium:aluminium ratio increased after contact. This can be explained by preferential release of aluminium from the additive particles (as observed in the migration tests), which can be explained by the fluoride-modified alumina being located as a surface treatment on the titanium dioxide particles.

iv) Migration tests from polyamide 66 using a dispersing alternative food simulant

Polyamide 66 plaques (made with the maximum intended use level of 25% w/w) were submitted to a migration test using an aqueous solution of a proprietary surfactant as an alternative food simulant. The surfactant is a mixture of ionic and non-ionic detergents and has found several applications in published work on nanomaterials. Tests confirmed that the additive could be dispersed into the surfactant solution and the dispersion remained stable without sedimentation for at least 1 week. In contrast, dispersions prepared by sonication in 3% acetic acid, water and water adjusted to pH = 9.5 with sodium hydroxide showed visible sedimentation after just 1 h. The migration test conditions using the surfactant solution were 4 h at 100°C, followed by 10 days at 60°C. The simulant from the migration test was analysed by asymmetric flow field flow fractionation (AF4) with detection using multiangle laser light scattering (MALLS) and by AF4-ICP-MS (monitoring Ti). The MALLS detector suffered from interferences from migrated oligomers, detected both for samples of polyamide with- and without the additive incorporated. The AF4-ICP-MS method was more successful and was validated to have a detection limit for additive particles (set as the lowest concentration standard analysed) of ca. 4 μg/6 dm^2 when considering the area of plastic exposed in the migration test cell. No migration of particles was detected in the exposed simulant samples. When the additive was spiked into the simulant and then subjected to the time-temperature migration conditions, the recovery was 95%. A standard addition of the additive into the exposed simulant at an equivalent of ca. 8 μg/6 dm^2 gave the expected detector response. Swelling of the polyamide specimens was demonstrated, since the specimens increased by approximately 4.5% in mass.

v) Abrasion tests

LDPE plaques (made with the maximum intended use level of 25% w/w) were submitted to a mechanical stress test, with quartz sand and vigorous motion on an orbital shaker for 60 min, to assess the potential release of particles as a result of abrasion with solid/dry foods. The sand and resulting abraded polymer/dust was quantitatively transferred into centrifuge vials using the proprietary surfactant solution (see above) as a dispersant. The mixture was shaken for 15 min to detach and disperse any released remaining additive particles. The sand was allowed to settle, and the supernatant analysed by AF4-MALLS and AF4-ICP-MS (monitoring titanium). No particulate material (measured by AF4-MALLS) and no particulate material containing titanium (measured by AF4-ICP-MS) was detected. The detection limit was established from the lowest concentration standard analysed, to be equivalent to ca. 3 μg/6 dm^2 when considering the area of plastic exposed in the abrasion test cell. When additive was spiked into sand, the recovery of the dispersion step was measured to be 98%. A standard addition of the additive into the used sand at an equivalent to ca. 6 μg/6 dm^2 gave the expected detector response using both techniques.

In conclusion, the Panel considered that these tests demonstrate that the additive particles stay embedded in the polymers made with the maximum intended use level of 25% w/w, including in polar polymers such as polyamides swollen by aqueous simulants, and do not migrate. The additive particles, when present at 25% w/w in polymers, also resist release by abrasion and do not transfer into a simulant for solid/dry foods. Migration of ionic species occurs from the surface of the additive particles and particularly from the swollen regions of the plastic where the simulant has better access to the additive. Aluminium, fluoride and, in a very limited extent, titanium are solubilised and migrate in ionic form.

3.2. Toxicological data

Based on the above-mentioned data, the additive particles stay embedded in the polymers and do not migrate, thus, do not give rise to exposure via food and to toxicological concern. The Panel considered that aluminium, fluoride and, in a very limited extent, titanium could be solubilised and migrate in ionic form. Therefore, the Panel considered the exposure from these entities.

Ionic titanium

Migration of titanium from the non-polar polymer was not detected at the LoD of 5 μg/kg food. Migration of titanium from the polar polymer after 4 h at 100°C, followed by 10 days at 60°C was just detectable at the LoD. Therefore, under the requested conditions of uses, the limited migration, if any, of titanium does not give rise to a safety concern.

Ionic fluoride

Concerning fluoride, the Panel considered the opinions from the EFSA AFC and NDA Panels, the WHO 'Guidelines for drinking-water quality' and the fluoride-containing substances that are authorised and listed in the Regulation (EU) No 10/2011. The EFSA NDA Panel set in 2013 an adequate intake (AI) from all sources of 0.05 mg/kg body weight (bw) per day for children and adults including pregnant and lactating women, because of the beneficial effects of dietary fluoride on dental caries. This corresponds to a range from 0.4 mg/day for a 7- to 11-month child to 3.4 mg/day for adults (≥ 18 years) (EFSA NDA Panel, 2013). Artificial fluoridation of water supplies is usually 0.5–1.0 mg/L (WHO, 2017) and WHO recommends a guideline value for fluoride of 1.5 mg/L based on 'epidemiological evidence that concentrations above this value carry an increasing risk of dental fluorosis and that progressively higher concentrations lead to increasing risks of skeletal fluorosis'. Fluoride is not authorised/listed as such; nevertheless, silicic acid, magnesium-sodium-fluoride salt (FCM number 685) is authorised under the Regulation (EU) No 10/2011 with a SML of 0.15 mg/kg food expressed as fluoride and a restriction on uses based on the opinion of the EFSA AFC Panel (EFSA, 2004). In its opinion, the AFC Panel considered that 'a concentration of fluoride in foods, migrating from food contact materials, not exceeding the 10% of the upper limit in drinking water poses no risk to human health'. Migration of fluoride from the non-polar polymer was up to 0.05 mg/kg food. From the polar polymer in contact for 4 h at 100°C with acidic food, migration was estimated to be 0.4 mg/kg food simulant and 3.6 mg/kg food simulant when the contact is followed by 10 days at 60°C, so exceeded in both contact conditions the 0.15 mg/kg SML.

Ionic aluminium

With regard to aluminium, the Panel considered the opinion of the AFC Panel that established in 2008 a tolerable weekly intake (TWI) of 1 mg/kg bw from all sources of aluminium (EFSA, 2008) and the SML of 1 mg/kg food derived from that TWI and applying an allocation factor of 10%. In 2011, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a provisional tolerable weekly intake (PTWI) of 2 mg/kg bw based on a new neurodevelopmental study in rats (Poirier et al., 2011). However, JECFA noted the complication of the identification of the lowest observed adverse effect level (LOAEL) and the no observed adverse effect level (NOAEL) from this study due to decreasing fluid consumption. The Panel also considered the more recent EFSA technical report (EFSA,

2013) which underlined that 'The mean and 95th percentile dietary exposure estimates to five aluminium-containing food additives for five population groups (toddlers, children, adolescents, adults and the elderly) largely exceed the TWI established by EFSA and the PTWI established by the JECFA'. Migration of aluminium from the non-polar polymer was up to 0.066 mg/kg food. From the polar polymer in contact for 4 h at 100°C with acidic food, migration was 0.54 mg/kg food simulant and 4.7 mg/kg food simulant when the contact was followed by 10 days at 60°C, so exceeding in the latter contact conditions the 1 mg/kg SML.

4. Conclusions

Based on the above-mentioned data, the CEP Panel concluded that under the intended and tested conditions of uses, the particles of the substance titanium dioxide surface treated with fluoride-modified alumina (including nano-particles) stay embedded in the polymers, do not migrate and resist release by abrasion, thus, do not give rise to exposure via food and to toxicological concern. There is migration of aluminium and fluoride in soluble ionic form from the surface of the additive particles, particularly upon swelling of the plastic.

The Panel concluded that the substance does not raise safety concern for the consumer if used as an additive at up to 25% w/w in polymers in contact with all food types for any time and temperature conditions. However, uses in polar polymers swelling in contact with foodstuffs simulated by 3% acetic acid should be limited to conditions simulated by contact up to 4 h at 100°C. This is due to the fact that when used at 25% w/w, and contact was followed by 10 days at 60°C, the migration of aluminium and fluoride largely exceeded the SML of 1 and 0.15 mg/kg food, respectively. Even when the substance is used in polar polymers swelling in contact with aqueous foodstuffs including acidic foodstuffs under conditions simulated by contact for 4 h at 100°C, the migration of fluoride could exceed the 0.15 mg/kg food SML.

The Panel emphasises that existing SMLs for aluminium and fluoride should not be exceeded in any case.

Remark to the Commission

The CEP Panel noted that the SML for substances migrating from FCM have been established considering as default scenario 1 kg of food consumed by a 60-kg bw adult, whereas infants and toddlers have a higher food consumption than adults when it is expressed per kg bw. This was acknowledged notably in the opinion of the CEF Panel on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials (EFSA CEF Panel, 2016), and more recently, in the EFSA Scientific Committee cross-cutting guidance on the risk assessment of substances present in food for infants below 16 weeks (EFSA Scientific Committee, 2017). Therefore, in case of plastics for which the intended or foreseeable uses include contact with foods for infants (such as bottled water, infant formula) or toddlers, the exposure of infants and toddlers to migrants from plastics could possibly exceed the allocated health-based guidance value when the SML is established using the adult exposure model.

Documentation provided to EFSA

1) Initial dossier. April 2014. Submitted on behalf of DuPont Titanium technologies.
2) Additional data. October 2015. Submitted on behalf of The Chemours Company (formerly DuPont Titanium technologies).
3) Additional data. October 2017. Submitted on behalf of The Chemours Company.
4) Additional data. January 2019. Submitted on behalf of The Chemours Company.
5) Additional data. April 2019. Submitted on behalf of The Chemours Company.

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Abbreviations

AF4	asymmetric flow field flow fractionation
AFC	Scientific Panel on Additives, Flavourings, Processing Aids and Materials in Contact with Food
AI	adequate intake
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Scientific Panel on food contact Materials, Enzymes and Processing Aids
EDS	energy-dispersive spectroscopy
FAO	Food and Agriculture Organization of the United Nations
FCM	food contact materials
ICP-MS	inductively coupled plasma mass spectroscopy
JECFA	Joint Expert Committee on Food Additives
LDPE	low-density polyethylene
LOAEL	lowest observed adverse effect level
LoD	limit of detection
MALLS	multiangle laser light scattering
MoS	Margin of safety

NDA	Scientific Panel on Dietetic products, Nutrition and Allergies
NOAEL	no observed adverse effect level
PTWI	temporary tolerable weekly intake
RSD	relative standard deviation
SCF	Scientific Committee on Food
SEM	scanning electron microscopy
SML	specific migration limit
TEM	transmission electron microscopy
TWI	tolerable weekly intake
WHO	World Health Organization
w/w	weight by weight