Exposure Assessment - Statement on the safety of Titanium Dioxide (E171) as a Food Additive

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Exposure Assessment

282. The exposures to TiO_2 from medication, personal healthcare products and through dermal, inhalation and intravenous routes are not considered in this assessment. The exposures considered are only those from food.

283. Titanium dioxide can be found in a number of food categories including bakery products, soups, broths, sauces, salads, savoury based sandwich spreads and processed nuts. It is also used in confectionary, chewing gum, food supplements and cake icing (EFSA, 2016).

Occurrence data in food

284. Only food as a source of TiO_2 is considered in this exposure assessment. Food consumption data from the National Diet and Nutrition Survey (NDNS) (Bates, 2014; 2016; Roberts 2018; Bates, 2020) and the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (Department of Health, 2013) were used to estimate exposure to titanium dioxide. Maximum occurrence levels of titanium dioxide for specific food items, reported by EFSA (2021), were also used in the

estimation of exposure (Table 6). Food categories were created by the FSA Exposure Assessment Team (EAT) using data from NDNS and DNSIYC to reflect those created by EFSA for the Food Additive Intake Model and as presented in Annex II of Regulation (EC) No 1333/2008, part D. Foods in NDNS and DNSIYC were matched to food categories associated with the regulation on food additives to enable an assessment of exposure based on maximum levels reported by industry for titanium dioxide and those reported in the scientific literature. Assessments were carried out in Crème which is the software used by the FSA EAT to conduct exposure assessments.

285. The occurrence data used were those reported in EFSA, 2021, which were obtained from industry as reported by the Dutch National Institute for Public Health and the Environment (RIVM), along with levels reported in analytical studies. These levels are presented in Table 6 for sixteen food categories, although titanium dioxide is approved in many other food categories (forty-eight in total) (Table 1, Annex C. For the exposure assessment, only use levels for these sixteen food categories were taken into account, as no data were available for the other categories and it was not possible to use the maximum permitted levels (MPLs) for TiO_2 as they were established at quantum satis, rather than a specific value being ascribed. The assessment was based on maximum use levels reported to provide conservative scenarios of exposure for the population groups considered (Table 7).

Table 6: Occurrence levels of titanium dioxide (E171) used in the exposure assessment scenarios (mg/kg or mg/L as appropriate)

EFSA Food category number	Food category name	Concentration levels used in the exposure assessment (Maximum reported)	MPL (mg/L or mg/kg as appropriate)

01.4	Flavoured fermented milk products including heat-treated products	48	QS
01.8	Dairy analogues, including beverage whiteners	125	QS
03	Edible ices	857	QS
05.2	Other confectionery including breath-refreshening microsweets	4,500	QS
05.3	Chewing gum	16,000	QS
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	20,000	QS
07.2	Fine bakery wares	318	QS
12.5	Soups and broths	193	QS
12.6	Sauces	4,000	QS
12.7	Salads and savoury-based sandwich spreads	3,000	QS
12.9	Protein products, excluding products covered in category 1.8	5,000	QS

14.1.4	Flavoured drinks	70	QS
15.2	Processed nuts	7,000	QS
16	Desserts, excluding products covered in categories 1, 3 and 4	200	QS
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children	26,950	QS
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children	26,950	QS

QS – quantum satis (no maximum numerical level is specified, and substances will be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled).

Exposure Estimation

286. Exposure assessments were carried out for the following population groups: Infants, toddlers, other children, adolescents, adults and the elderly. There are two toddler groups. One group represents ages 1 - 1.5 years and the data used were from DNSIYC as this survey covers infants and young children aged 4 - 18 months (1.5 years). The other toddler group covers ages 1.5 - 3+ years and data were obtained from the NDNS, as this survey covers all age groups from 1.5 years. The mean and 95th percentile estimates are presented for

each population group and food category in mg/kg bw per day in Table 7.

287. The reported data are consumer-based, meaning that only subgroups of the population that consumed these categories of food were considered. The mean and 95th percentile total exposures are derived from the combined exposure for each individual in the respective age group. The mean and 95th percentile total exposures have not been derived by adding up the mean and 95 th percentile values respectively, for the food categories, as not all consumers will be exposed in each category. Total exposures were calculated to estimate exposures from the total diet in Table 8. These were calculated from a distribution of individual total exposure of any combination of food categories, rather than by summation of the respective mean/95th percentile consumption values for each of the food categories.

288. The mean calculated total exposures for TiO_2 from foods ranged from 3.3 to 11 mg/kg bw per day. The 95th percentile total exposures for TiO_2 ranged from 9.1 to 26 mg/kg bw per day. The 3 food groups that contribute the most to these exposures are: protein products; Decorations, coatings and fillings, except 4.2.4; and Sauces.

Table 7: Estimated mean and 95th percentile (P95) exposures (mg/kg bw per day)a to titanium dioxide E171 from its use as a food additive based on the maximum reported use level. The reported data are consumer-based.

Food group
1.4- Flavoured fermented milk products including heat-treated products
1.8. Dairy analogues and whitener
12.5. Soups and broths
12.6. Sauces

12.7. Salads and savoury based sandwich spreads

12.9. Protein products

14.1.4. Flavoured drinks

15.2. Processed nuts

16. Desserts excluding products covered in categories 1, 3 and 4

17.1. Food supplements supplied in a solid form, excluding for infants and young child

17.2. Food supplements in a liquid form, excluding for infants and young children

3. Edible ices

5.2. Confectionery and sweets

5.3. Chewing gum

5.4. Decorations, coatings and fillings, except 4.2.4
7.2. Fine bakery wares

*Estimates are rounded to 2 significant figures.

**Calculated from a distribution of individual total exposure of any combination of food categories rather than by summation of the respective mean/95th percentile consumption values for each of the food categories.

[a] Exposure per bodyweight was calculated for each individual before calculating the mean and P97.5 exposure. The mean and 95th percentile estimates are presented for each population group and food category in mg/kg bw/day in Table 2. The estimates are based on individual bodyweights and not the average for the population group. However, for context, the average bodyweights of the population groups are 9.11 kg for infants; 10.9 kg for 12-18 months old; 14.6 kg for 1.5 -3 years; 27.1 kg for 4-10 years; 58.9kg fo r 11-18 years; 78.6 kg for 19-64 years; and 70. 6kg for the elderly.

[b] 95th percentile exposures have been reported for the UK to aid the comparison with data reported by EFSA.

Table 8: Estimated mean and 95th percentile (P95) total exposures (mg/kg bw/day)a to titanium dioxide E171 from its use as a food additive based on the maximum reported use level.

Age Group	**Infants** (4 – 11 months) **Mean** **(P95[b])**	**Toddlers** (1 - 1.5 years) **Mean** **(P95[b])**	**Toddlers** (1.5 - 3 years) **Mean** **(P95[b])**	**Children** (4 - 10 years) **Mean** **(P95[b])**	**Adolescents** **(**11 - 18 years) **Mean** **(P95[b])**	**Adults** (19 - 64 years) **Mean** **(P95[b])**
Total exposure**	3.9 (14)	6.9 (19)	11 (26)	9.5 (24)	5 (13)	3.7 (10)

[a] Exposure per bodyweight was calculated for each individual before calculating the mean and P97.5 exposure. The mean and 95th percentile estimates are presented for each population group and food category in mg/kg bw per day in Table 2. The estimates are based on individual bodyweights and not the average for the population group. However, for context, the average bodyweights of the population groups are 9.11 kg for infants; 10.9 kg for 12-18 months old; 14.6 kg for 1.5 -3 years; 27.1 kg for 4-10 years; 58.9 kg for 11-18 years; 78.6 kg for 19-64 years; and 70.6 kg for the elderly.

[b] 95th percentile exposures have been reported for the UK to aid the comparison with data reported by EFSA.

** The total exposure includes all of the following food groups:

1.4- Flavoured fermented milk products including heat-treated products

1.8. Dairy analogues and whitener

12.5. Soups and broths

12.6. Sauces

12.7. Salads and savoury based sandwich spreads

12.9. Protein products

14.1.4. Flavoured drinks

15.2. Processed nuts

16. Desserts excluding products covered in categories 1, 3 and 4

17.1. Food supplements supplied in a solid form, excluding for infants and young children

17.2. Food supplements in a liquid form, excluding for infants and young children

3. Edible ices

5.2. Confectionery and sweets

5.3. Chewing gum

5.4. Decorations, coatings and fillings, except 4.2.4

7.2. Fine bakery wares