

## Titanium Dioxide

In different recent food safety meetings, the new developments regarding Titanium Dioxide have been addressed.

Previously the safety concern was mainly related to the presence of a nanoparticles and the inhalation of TiO<sub>2</sub>.

At the International Agency for Research on Cancer (IARC) TiO<sub>2</sub> dust is classified as a Group 2B carcinogen, which means “possibly carcinogenic to humans” (See FC update 28/11 2019) and in the CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging, the substance has been classified (February 2020) in category 2, as a suspected carcinogen when inhaled.

This CLP classification will be binding from the 1/10 2021 and means the “health hazard” warning label (GHS 08) with the statement “suspected of causing cancer (inhalation)” will have to be present on the packaging of Titanium Dioxide, when in powder form containing 1% or more of particles with an aerodynamic diameter  $\leq 10 \mu\text{m}$ .

In case TiO<sub>2</sub> is present in liquid or solid mixtures the Commission Delegated Regulation (EU)2020/217 specifies how a label on the packaging of the concerned product shall bear specific statements:

EUH 211 “Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.”

EUH 212 “Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.”

In case the product is not intended for the general public, the packaging needs to bear in addition, EUH 210 “Safety datasheet available on request”.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0217&from=EN>

New is the raising concern related to the use of Titanium Dioxide (E171) as a food additive.

France adopted in 2019 a ban on food containing E171 for one year starting from January 2020 (See FC update 28/11 2019) and this ban appears to have been extended into 2021, but now in May EFSA has issued a new assessment on the use of Titanium Dioxide as a food additive.

<https://www.efsa.europa.eu/en/news/titanium-dioxide-e171-no-longer-considered-safe-when-used-food-additive>

*The abstract of the scientific opinion explains, studies on general and organ toxicity did not indicate adverse effects with E171 up to a dose of 1000 mg/kg body weight (bw) per day or with TiO<sub>2</sub> Nanoparticles NPs (> 30nm) up to the highest dose tested of 100 mg/kg bw per day.*

*No effects on reproductive and developmental toxicity were observed up to a dose of 1000 mg E 171 bw per day, the highest dose tested. However, observations of potential immunotoxicity and inflammation with E171 and potential neurotoxicity with TiO<sub>2</sub> NPs, together with the potential induction of aberrant crypt foci (= clusters of abnormal tube-like glands in the lining of the colon and rectum) with E171, may indicate adverse effects. With respect to genotoxicity, the Panel concluded that TiO<sub>2</sub> particles have the potential to induce DNA strand breaks and chromosomal damage, but not gene mutations. No clear correlation was observed between the physico-chemical properties of the TiO<sub>2</sub> particles and the outcome of either in vitro or in vivo genotoxicity assays...*

Based on all the evidence available, a concern for genotoxicity could not be ruled out, and given the many uncertainties, the EFSA Panel concluded that E171 can no longer be considered as safe when used as a food additive.

Although it needs to be stressed the new EFSA evaluation is only related to the risks of TiO<sub>2</sub> used as a food additive and not to the other uses, it is useful to obtain data on the migration behaviour of the substance.

At a recent Commission meeting the EFSA opinion was discussed, and one of the Member States asked already after the use of Titanium Dioxide in other applications.

Helpful in this sense is the statement from the ink manufacturers association (EuPIA) in which reference is made to two studies commissioned by the German Paint and Printing Ink Association VdL (2013 and 2020), aimed at investigating the migration behaviour of nano-scale pigment particles from printed food



contact materials into food, both during non-direct as well as direct contact of the printing ink layer with foodstuff.

Both studies also included nano-scale titanium dioxide pigment particles and the studies confirmed the absence of any migration or set-off, of these particles into food.

[https://www.eupia.org/fileadmin/user\\_upload/2021-05-11\\_EuPIA\\_Statement\\_on\\_the\\_EFSA\\_opinion\\_on\\_TiO2.pdf](https://www.eupia.org/fileadmin/user_upload/2021-05-11_EuPIA_Statement_on_the_EFSA_opinion_on_TiO2.pdf)

## Endocrine disruptors

As reported (FC update 5/02/21) France notified a Decree on the presence of EDCs in products. The Decree specifies, information needs to be provided on articles placed on the French market, containing EDC substances.

The way of implementation remains unclear, but ANSES the French Food Safety Agency published a list with 906 EDC substances of which 16 are prioritised.

<https://www.anses.fr/en/content/accelerating-assessment-endocrine-disruptors>

Of those prioritised substances, 8 are included in the Food Contact Chemicals Database (See FC update 22/12 2020) indicating they may be used in food contact materials.

The FCCdb allows e.g., to identify the origin for the prioritisation (authoritative and non-authoritative sources), the FCM reference legislations in which the substance is listed and the presence of the substance on the global substance inventories per Food Contact Material.

CAS number		Prioritized in FCCdb FPF based on authoritative sources.	Potential concern based on non-authoritative sources.	Plastics Reg. 10/2011	Swiss Ink Ord.	BfR 36	BfR Food Contact Adhesives	Inventory					
								Plastics	Coatings	P&B	Adhesiv.	Colorant	Inks
127-18-4	Tetrachloroethylene	HH + ENVH, P65	putative EDC TEDX, potential vPvM & PMT, SIN list	-	-	-	-	X	X	X	X	-	-
100-41-4	Ethylbenzene	HH, P65	putative EDC TEDX	-	List A	-	-	X	X	X	-	-	X
92-88-6	4,4'-Biphenyldiol	-	putative EDC TEDX	X	-	-	-	X	X	-	-	-	X
7773-01-5	Manganese(II) chloride	-	putative EDC TEDX	X	List A	-	-	X	X	X	X	-	X
1344-09-8	Sodium hydroxy(oxo)silanolate	-	putative EDC TEDX	-	-	X	X	X	X	X	X	-	-
102-71-6	Triethanolamine	-	putative EDC TEDX	X	List A	X	-	X	X	X	X	-	X
7681-49-4	Sodium fluoride	-	putative EDC TEDX	-	-	-	-	X	-	X	-	-	-
557-34-6	Zinc acetate	-	putative EDC TEDX	-	-	-	-	X	-	-	-	-	-

HH : present on inventories for health hazards aligned with Globally Harmonised System (GHS).  
 ENVH : present on inventories for environmental hazards.  
 P65 : Californian Proposition 65  
 TEDX : The Endocrine Disruption Exchange list of potential EDCs.  
 vPvM / PMT : very persistent, very mobile / Persistent, Mobile, Toxic  
 SIN list : the "Substitute It Now" list maintained by the NGO Chemical Secretariat (Chemsec)

## WTO notification German Mineral Oil Regulation

Based on the discussions in the Food Safety Committee meeting (29/04), ECMA issued an additional position repeating once more all objections against the German mineral oils regulation

The position now written in the context of the WTO notification was shared with the members and the national associations for use with the national food safety authorities. (ECMA mail 10/05)

<https://www.ecma.org/news/messages/ecma-statement-wto-notification-german-mineral-oil-ordinance.html>

## Consultation on UV lamps.

Mid May ECMA was alerted on the risk UV lamps containing mercury may be banned for environmental reasons.

ECMA supported in the consultation process, the request submitted by the VDMA and Lightning



Europe, aiming for an extended exemption of another 5 years. Such an exemption was previously granted in 2015 and 2020.

Experts from the Food Safety Committee confirmed that UV technology with this type of mercury-containing lamps is still widely used in the sector, providing safe operation and how the lamps after use are collected by specialised companies to prevent mercury from being released into the environment at converting operations.

Alternatives are not available at the moment. Lamps based on iron, gallium etc. do not cover the necessary spectrum, which is crucial for accurate curing.

LEDs are not an alternative for packaging either, because the spectrum is very limited and the existing materials are largely unsuitable for food packaging.

Electron beam curing is still technically not feasible in sheet-fed offset carton printing and may also present significant potential hazards.

### **Single Use Plastics Directive**

The 31/05 the final Commission guidelines on single use plastic products in accordance with the SUPD, were released. (See ECMA member mail 2/06)

Paper cups and food containers with a plastic coating or lining (irrespective of their thickness) and fulfilling the 3 criteria for being part of the SUPD scope, will be subject to consumption reductions.

As noted in the ECMA Food Safety Committee, the text contains contradictions!

The text acknowledges, in the production of many non-plastic materials, polymers (meeting the definition of plastic) are used as synthetic chemical additives and the text specifies further:

“The use of such polymeric materials, e.g. as retention agents or binders and processing aids in the production of a material, which in itself is not plastic, does not result in the single-use product made only of that material to be considered as being made partly of plastic.” (Guidelines paragraph 2.2.1)

All this means certain chemicals can be used in cardboard manufacturing or in the exempted inks and adhesives (SUPD Recital 11), while their use in any amount at the surface of a carton as a “lining or coating” with the functionality to provide protection against water of fat, classifies the carton as a composite product. (?)

As these Guidelines represent the views of the Commission and as such are not legally binding, further discussions at Member State level are to be expected.

