

PQRI Workshop:
TiO₂ Use in Pharmaceuticals
Global Regulatory and Technical Challenges

Breakout Session 1: June 13, 2023

Scientific Understanding & Awareness of the Safety of TiO₂

Moderators:

Uma Bruen
George Collins

Notetakers:

Kevin Hughes
Courtney Callis



Breakout Session Ground Rules

- Day 1 break-out session is 1 hour 15 minutes; therefore, there is limited time for discussion for each question (approx. 10 minutes per question). It is the intent of the program committee to get comments from as many attendees as possible, **so please**
 - **Be concise with your questions and comments**
 - **Allow time for other attendees in the breakout session time to voice their comments and/or questions**
 - **Respect when the facilitator announces that it is time to move to the next question**



TiO₂ History of safe use (Group 1: toxicologists, safety experts)

1. Hazard is not Risk: Should the assessment EU conducted (which is different from rest of the world) have been based on real risk versus hazard potential?
 - How many Skittles do you need to eat for there to be a safety concern? An adult would have to eat 4,080 skittles – each and every day – for over 9 years – to achieve the genotoxic dose in someone's spleen,
 - How many TiO₂-coated tablets do you need to take for there to be a safety concern? Estimated 681 tablets per 6 hrs to achieve some measure of toxicity
2. Should a Maximum daily exposure level be assigned to TiO₂, and how should this be done?
 - How do arrive at an ADI? What data/study could be used, exposure duration, route of exposure, etc.?
 - Can we ask industry to provide this?
3. Do you agree with EFSA that a concern for genotoxicity cannot be excluded, or with the expert panel that there is no evidence of direct genotoxic activity, or are you unable to reach a conclusion and believe more data is needed?
4. If you believe more data is needed, what do you think of the new genotoxicity studies proposed by TDMA?
5. The NTP performed a GLP 2- year bioassay in rats and mice involving administration of a TiO₂ similar to E171 up to 5% of the diet without any evidence of carcinogenicity or preneoplastic changes, including in the colon. Should this be considered adequate demonstration of its lack of carcinogenic activity?



Public Education/Perception of TiO₂ safety (Group 2 : Safety, marketing, communication professional)

- 1 . What type of communication tools should be created to provide more understanding of the safety of TiO₂? Especially to public understanding/awareness?
 - FAQ on TiO₂, consumer knowledge, perception,
 - Example: TiO₂ exposure thru food, maybe estimate number of Skittles you need to eat to be safety concern (e.g. 4080 per day for 9 years)
 - How many TiO₂-coated tablets do you need to take for there to be a safety concern? Estimated 681 tablets per 6 hrs to achieve some measure of toxicity
- 2 . How do we effectively communicate/educate the “safety of TiO₂” to consumers, public, politicians?
 - You tube video? Programs, factsheets? Graphical presentation/Imaging on Safety of TiO₂
 - How do we get this messaging thru to public in format that is understood?
- 3 . In Dr Cohen’s talk, Weight of evidence presented indicates E171 has none of the properties for it to be human carcinogen. What may be simple way to help public understand “weight of evidence” concept for help the understand “TiO₂ history of safe use”?
4. With the presentations given today, do you believe TiO₂ should be banned as a food additive?
 - a. Full ban: no TiO₂ in the formulation
 - b. Limited
 - c. Nanoparticles TiO₂
5. Should Politics override the science?

