

Second, you asked if FDA was aware of “the severe toxic cumulative effect of free methanol in the body, building up over time (0-20 years) eventually causing organ, tissue and neurological damage.” FDA is not aware of any information that substantiates this claim as it relates to methanol exposure from the use of aspartame. From the data reviewed by FDA, methanol in aspartame (or in fruits and juices) does not accumulate in the body and is easily metabolized by the body’s metabolic capacities. One would have to be exposed to repeated doses of methanol at levels well above those resulting from consumption of aspartame-containing food products before any accumulation would occur.

As stated in previous FDA responses to you, FDA established an acceptable daily intake (ADI) for aspartame of 50 milligrams per kilogram of bodyweight per day (mg/kg bw/d) from the evaluation of safety information submitted in the food additive petition for the use of aspartame in carbonated beverages. In your letter dated March 21, 2011, you asked how the American ADI for aspartame could be higher than UK’s ADI. You also noted that the UK used a no observed adverse effect level (NOAEL) of 4000 mg/kg bw/day in rats to determine their ADI. The difference between the UK’s ADI and the American ADI (established by FDA) is due to two factors: 1) they are based on different studies and doses; and 2) they apply different safety factors. While the UK’s ADI is based on a NOAEL of 4000 mg/kg bw/day in rats, the American ADI is based on a no observed effect level (NOEL) of 200 mg/kg bw/day in humans. The 200 mg/kg bw/day NOEL in humans was based on detailed FDA scientific review of extensive clinical testing of different human subpopulations. Regarding safety factors, the UK applies a 100-fold safety factor, which yields an ADI of 40 mg/kg bw/day human consumption of aspartame. FDA originally applied the same 100-fold safety factor to an FDA established NOEL of 2000 mg/kg bw/day in rats, which yielded an ADI of 20 mg/kg bw/day. However, upon consideration of the reassuring results from a broad range of clinical studies which looked at the impact of aspartame consumption in humans, FDA had increased certainty about the safety of aspartame and applied a 4-fold safety factor to the NOEL of 200 mg/kg bw/day in humans, which yields the current American ADI of 50 mg/kg bw/day.

FDA has fully evaluated the safety related to dietary levels of methanol derived from aspartame and previously concluded that these levels do not represent uncommon or toxic levels of exposure. The American ADI of 50 mg/kg bw/day of aspartame (or 5 mg/kg body weight of methanol) results in between 20- and 160-times less methanol exposure than would result from the aspartame doses (1-8 gm/kg bw/day) the rats received. FDA has concluded that consumption of aspartame is well below the acceptable daily intake, that it is safe for its intended use, and that high levels of human aspartame intake are unlikely to exceed the ADI when it is used in food under current good manufacturing practice.