

FDA Labeling Requirements: What regulations have we followed or exceeded?

The FDA requires us to list trace elements as ingredients that are above 10ppm/serving.

"7. Is it necessary to declare trace ingredients?

Answer: It depends on whether the trace ingredient is present in a significant amount and has a function in the finished food. If a substance is an incidental additive and has no function or technical effect in the finished product, then it need not be declared on the label. **An incidental additive is usually present because it is an ingredient of another ingredient**. Sulfites are considered to be incidental only if present at less than 10 ppm. 21 CFR 101.100(a)(3)"

1 teaspoon of Adya Clarity treats approximately 1.3 gallons of water, at this proper dilution ratio, there is approximately 1.1ppm of aluminum sulfate which is nearly 10x less than what the FDA requires for listing of a trace element on the label. **Despite this requirement, we have decided to include aluminum as well as other trace minerals on the label.** Remember, Adya Clarity is an extract of Biotite Mica in it's complex sulfate ionic form, it is not a mineral solution of different minerals added together. In other words, the aluminum, iron, and other minerals come as one whole complex form as it would from a natural sulfate spring.

Adya inc. is not responsible for off-label use of the product. Note to Consume