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## **Summary Expert Opinion Concerning the Generally Recognized as Safe (GRAS) Status of Velositol<sup>®</sup> Amylopectin/Chromium Complex as Generally Recognized as Safe (GRAS) in Select Food Categories**

**May 25, 2017**

At the request of Nutrition 21, LLC (Nutrition 21 hereafter), the undersigned, an independent recognized expert (hereinafter referred to as Expert), qualified by scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, assessed the use of Velositol<sup>®</sup> amylopectin/chromium complex. The chromium complex component of Velositol<sup>®</sup> consists of both chromium picolinate, as a stable complex of trivalent chromium (Cr<sup>+3</sup>) and picolinic acid, and chromium histidinate, a stable complex of trivalent chromium and histidine. The Expert was asked to determine whether Velositol<sup>®</sup> amylopectin/chromium complex is Generally Recognized as Safe (GRAS) for use in the United States (U.S.) as a source of trivalent chromium in meal replacement beverages including protein drinks (ready-to-drink and powder types) and meal replacement bars, energy bars, and protein bars in an amount equivalent to 1,000 µg Cr<sup>+3</sup>/serving.

Nutrition 21's Velositol<sup>®</sup> amylopectin/chromium complex is manufactured in accordance with current Good Manufacturing Practices (cGMP). Batch analysis data indicate the manufacturing process results in a product that consistently meets specifications. Stability data demonstrate Velositol<sup>®</sup> amylopectin/chromium complex remains stable under these conditions for up to 24 months.

Both chromium histidinate and chromium picolinate are considered GRAS<sup>3</sup> ingredients approved for use in foods under conditions of use identical to those proposed for Velositol<sup>®</sup>. The remaining component, amylopectin, meets the definition for food starch-modified and is approved for use as a food additive under 21 CFR 172.892.

The Expert critically examined a comprehensive package of scientific information and data compiled from the publicly available literature through March of 2017. The safety of trivalent chromium, such as that present in Velositol<sup>®</sup> amylopectin/chromium complex is supported by its status as an essential nutrient. In addition, the Expert reviewed safety studies conducted with chromium complexes (chromium histidinate, chromium picolinate and chromium polynicotinate). Available data to support the safety of trivalent chromium include subacute and subchronic toxicity studies, reproductive and developmental toxicity studies, carcinogenicity studies, and genotoxicity studies of various chromium complexes (*i.e.*, chromium picolinate, chromium histidinate, and chromium polynicotinate). The NOAEL in the 2-year study was considered to be 2,400 mg/kg body weight/day of chromium picolinate monohydrate, equivalent to approximately 300 mg of Cr<sup>+3</sup>/kg body weight/day.

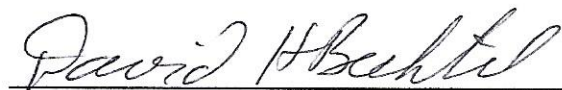
The Expert noted that amylopectin, meeting the definition for food starch-modified, is approved for use as a food additive under 21 CFR 172.892. The Expert considered this approval as evidence of safety under the intended conditions of use of Velositol®.

Finally, the Expert considered that the proposed uses of Velositol® amylopectin/chromium complex would result in consumer-only mean and 90<sup>th</sup> percentile intakes of trivalent chromium by the total U.S. population of 1.6 mg/person/day (22.8 µg/kg body weight/day) and 3.4 mg/person/day (51.2 µg/kg body weight/day), respectively. The NOAEL of 2,400 mg chromium picolinate monohydrate/kg bw/day in a lifetime carcinogenicity study of the most sensitive sex and species is equivalent to approximately 300 mg of trivalent chromium/kg body weight/day (comparable to 18,000,000 µg trivalent chromium/day for a 60 kg human). The Expert noted that the NOAEL provides a safety factor of over 5000 compared to the calculated 90<sup>th</sup> percentile all-user intake of 51.2 µg/kg bw/day from the proposed conditions of use in food.

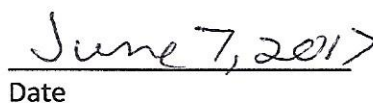
## CONCLUSION

Having considered all the relevant information, it is my opinion as a qualified expert that there is reasonable certainty that no harm will result from the intended use of Nutrition 21's Velositol® amylopectin/chromium complex, meeting the proposed food-grade specifications and manufactured in accordance with current Good Manufacturing Practices (cGMP), for use in the U.S. as a source of trivalent chromium in meal replacement beverages including protein drinks (ready-to-drink and powder types) and meal replacement bars, energy bars, and protein bars at 1,000 µg Cr<sup>+3</sup>/serving. It is my opinion that such use of Velositol® would be considered Generally Recognized as Safe (GRAS) through scientific procedures, and would be consistent with the GRAS conclusions for both chromium histidinate and chromium picolinate, and the approval of amylopectin as a food additive, making Nutrition 21's Velositol® exempt from the premarket approval requirements outlined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (U.S. FDA, 2015d).

On the basis of the information reviewed herein, the use of Velositol® amylopectin/chromium complex as an ingredient in foods in accordance with the conditions of use proposed herein is reasonably anticipated to be safe. As a result, Velositol® amylopectin/chromium complex may be considered Generally Recognized as Safe (GRAS) for the uses proposed herein through scientific procedures.



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Date