

**GENERALLY RECOGNIZED AS SAFE DETERMINATION FOR  
HYDROGEN WATER PRODUCED USING A TABLET  
CONTAINING ELEMENTAL MAGNESIUM**

**Prepared for:**

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## EXPERT PANEL STATEMENT

We, the members of the Expert Panel, qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food, have performed a comprehensive and critical review of available information and data on the safety and Generally Recognized As Safe (GRAS) status of a magnesium tablet to generate hydrogen water. The intended use of the magnesium tablet to generate hydrogen water has been determined to be safe and GRAS using scientific procedures, under the Federal Food, Drug, and Cosmetic Act (FFDCA), Section 201(s), based on the following:

- Magnesium tablets contain magnesium, malic acid, tartaric acid, sugars, flavors and lubricants that when added to water, generate a hydrogen water beverage.
- The magnesium tablet consists of food grade or pharmaceutical grade ingredients and is produced in a facility that complies with current Good Manufacturing Practices (cGMP) for dietary supplements.
- FDA filed, without comment, NDIN #2018001104 for the magnesium tablet described in this GRAS dossier, (a mixture of elemental magnesium, malic, and tartaric acids delivered in the form of a tablet and added to water, producing hydrogen water) on February 12, 2019.
- The safety of Natural Wellness Now hydrogen water is supported by numerous published studies of this source and other sources of hydrogen water in animal models and clinical studies. In addition, an evaluation of the toxicological relevance of the compositional differences between the hydrogen water tested in the toxicology studies and Natural Wellness Now hydrogen water confirms that studies of hydrogen water from other sources may be used to support the safety of Natural Wellness Now hydrogen water.
- FDA had no questions in response to a previous GRAS determination (GRN 520) for the use of hydrogen gas in bottled liquids. GRN 520 determined that 3.2 mg/day of hydrogen was safe and GRAS (the amount of hydrogen consumed based on the assumption that maximum intake of water per day is 2 L and hydrogen is present at saturation).
- The compositional difference between the hydrogen water tested in the toxicology studies (which use either magnesium sticks placed in drinking water or a hydrogen-bubbling apparatus) and Natural Wellness Now hydrogen water is the presence of

magnesium malate, magnesium tartrate, and magnesium hydroxide, which are formed from the reaction that is used to generate hydrogen water from the magnesium tablets. Magnesium hydroxide is also generated from using magnesium sticks in water to generate hydrogen water.

- Magnesium malate and magnesium tartrate are soluble and will dissociate into magnesium, malic acid and tartaric acid. The EDI for both malic and tartaric acid conform with the GRAS requirement of no limitation for use other than GMP as defined in their respective CFR citations. Thus, there is no concern for an adverse health outcome from exposure to malic or tartaric acids from consumption of hydrogen water.
- The Estimated Daily Intake (EDI) for magnesium from consumption of hydrogen water at the EDI contributes to the RDA for magnesium. Mean EDI for magnesium is 160 mg/person/day and a 90<sup>th</sup> percentile intake is 320 mg/person/day.
- Magnesium hydroxide is GRAS with no use limitation other than GMP (21 CFR§184.1428). The EDI of magnesium hydroxide from hydrogen water is also well below the intake that produces laxation from milk of magnesia, of which magnesium hydroxide is the active ingredient. Thus, the intake of magnesium hydroxide is reasonably expected to not produce any adverse gastrointestinal effects.
- Hydrogen water is generated by the addition of a maximum of one tablet (containing 80 mg of magnesium) to one bottle of water containing approximately 600 mL. The user then consumes the resulting hydrogen water beverage.
  - The mean and 90th percentile intakes of hydrogen water are approximately 1161 and 2322 mL/day.
  - Hydrogen gas has been deemed GRAS (GRN 520), for use in drinking water and flavored beverages up to 2.14% by volume (1.6 mg/L; 1.6 ppm; 0.8 mM), the saturation level of hydrogen gas in water at room temperature. Under the intended conditions of use (hydrogen water is generated by the addition of one tablet containing 80 mg of magnesium to one ~600 mL bottle of water), at the mean and 90th percentile intakes of water, the consumption of Natural Wellness Now Hydrogen Water will deliver a similar amount of hydrogen gas as the hydrogen gas described in GRN 520.

- Numerous published animal studies have investigated the use of orally administered hydrogen water at concentrations of hydrogen gas ranging from 0.08-0.8 mM for durations ranging from 1 day up to 12 months. No adverse effects of hydrogen water consumption have been reported in any of these studies.
- No adverse events were reported in numerous published clinical trials investigating the use of hydrogen gas in bottled water.

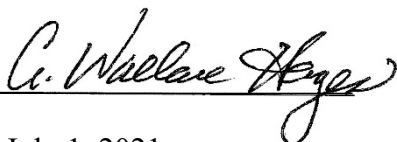
Therefore, the magnesium tablet added to water to generate a hydrogen water beverage is safe and GRAS at the proposed levels. The magnesium tablet is, therefore, excluded from the definition of a food additive, and may be used in the U.S. without the promulgation of a food additive regulation by the FDA under 21 CFR.

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