



## AP-24<sup>®</sup> WHITENING FLUORIDE TOOTHPASTE

The safety of our products is extremely important to Nu Skin. Nu Skin was founded on the belief that it could develop products containing beneficial and truly effective ingredients. This commitment to product quality and innovation remains the company's long-standing priority. Nu Skin relies on major governmental and regulatory bodies to decipher whether an ingredient is safe to use. Nu Skin continues to monitor the latest research on ingredient safety to maintain the highest standard of safety and quality.

The scientific committees that review these studies are associated with organizations such as the European Scientific Committee on Consumer Products (SCCP), Personal Care Products Council (PCPC), the Environmental Protection Agencies (EPA) in the United States and other European Countries, the Food and Drug Association (FDA), American Medical Association (AMA) - to name just a few. These review boards are made up of unbiased, educated and qualified scientists and professionals that understand the methods of scientific research and have a great deal of knowledge in these specific areas. These committees examine all the available studies on a given ingredient and determine whether it is safe for human application and the environment as presently used in cosmetics. As these are qualified scientists and professionals, they do not take each study at face value. Rather, they weigh the study based on the use of the ingredient, its dose, how the research was conducted and other factors when evaluating its application to human health.

AP-24 Fluoride Whitening Toothpaste was developed based on these same standards. Each ingredient within in this formula is included at a safe and efficacious amount per the available research. Dosing of ingredients or their concentration greatly impacts their safety. What is safe at one level, could be dangerous at another and completely ineffective at yet another. Skilled scientists and formulators ensure the final product is safe, effective and pleasing the end user. None the less, due to individual differences there is a chance of irritation with this or any product. If this occurs, the product should be discontinued.

### Fluoride

The USFDA has approved fluoride as an Over the Counter (OTC) drug in the US. The inclusion of fluoride such as, sodium fluoride, sodium monofluorophosphate, and stannous fluoride, is needed at an effective dose to make any anticaries claims for products. The use of fluoride in toothpastes has been thoroughly vetted and found to be safe and effective for prevention of dental cavities (decay, caries). The American Dental Association mandates that any product with its seal of approval have fluoride per the final US FDA monograph. For more information on fluoride use and safety see Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph; 21 CFR parts 310, 355, and 369. For information on fluorosis, see <http://www.mouthhealthy.org/en/az-topics/f/fluorosis>.

### Aluminum Hydroxide (Alumina)

Aluminum Hydroxide is a stable form of aluminum utilized in many personal care products including toothpaste. In toothpaste, it is included as an abrasive to help remove plaque and surface stains. The Cosmetic Ingredient Review Panel has reviewed aluminum hydroxide stating that this ingredient's use in cosmetics is chemically equivalent to that used in OTC antacid product. They also indicate that aluminum hydroxide should not be confused with elemental aluminum as these are substantially different in terms of physical properties, chemical properties, functions, and potential for toxicity. As such, aluminum hydroxide is poorly absorbed. They further concluded that they were "not concerned with the potential for incidental ingestion of alumina when used in lipsticks or oral hygiene formulations. The amount of the aluminum ion that could be released in the digestive tract through the incidental ingestion of such cosmetic products are far below the levels of toxicological concern." See Becker, L.C. et al. Safety Assessment of Alumina and Aluminum Hydroxide as Used in Cosmetics. IJT 35(Suppl. 3):16-33, 2016

### Sodium Lauryl Sulfate

After reviewing the available scientific literature, the Cosmetic Ingredient Review Panel has indicated that sodium lauryl sulfate is safe when used in “formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin” similar to its use in toothpaste formulations. Oral consumption studies, including those in quantities much larger than what would be expected from ingestion of oral hygiene products, did not show any toxicity concerns. See Final Report on the Safety Assessment of Sodium Lauryl Sulfate and Ammonium Lauryl Sulfate. *J Am Coll Toxicol* 2(7): 127-181, 1983

### Hydrated Silica

Concerns involving the abrasiveness of hydrated silica need to take into consideration the formulation of the final product. Silicates, such as hydrated silica, are specifically mentioned as examples of mild abrasives used to remove debris and surface stains and is specifically listed on the ADA website as typical toothpaste ingredients. The RDA, which measure the potential abrasiveness of a toothpaste, of AP-24 Whitening Fluoride Toothpaste is 103. This is well below the limit considered safe for daily use. See <http://www.ada.org/en/member-center/oral-health-topics/toothpastes>.

### Titanium Dioxide

Titanium dioxide is an approved food colorant that helps to make products aesthetically more pleasing. The health concerns relative to titanium dioxide revolve around its inhalation. Within personal care formulations, the titanium dioxide is bound and therefore does not have the ability to be inhaled. It, therefore, does not pose any of the same concerns. For more safety information on Titanium dioxide, see <http://www.cosmeticsinfo.org/ingredient/titanium-dioxide>.

### PEG-12

Acting as a humectant, PEG-12, is a polymer of ethylene glycol. Research on this ingredient indicates that is minimally absorbed. The ingredient used within our formulas is processed to remove 1,4 dioxane concerns. Thus, this ingredient does not pose any health or safety concerns. For more information on the safety of PEG-12, see <http://www.cosmeticsinfo.org/ingredient/triethylene-glycol-and-pegs>.

### Sodium Saccharin

The ADA website lists saccharin as an example of a typical toothpaste ingredient for flavoring agents. While early research on saccharin called its use into question, more recent studies have evaluated these concerns and found them unreasonable for humans. Additionally, saccharin and sodium saccharin were delisted from the Proposition 65 list more than a decade ago. For more information on the safety of sodium saccharin, see <http://www.cosmeticsinfo.org/ingredient/saccharin-and-its-calcium-and-sodium-salts>.