

## Whitening Toothpastes

**Product names (dates of ADA Acceptance):** Crest Extra Whitening With Tartar Protection Toothpaste (received ADA Seal of Acceptance in September 1999), Crest Multicare Whitening Toothpaste (February 2000), Colgate Tartar Control Plus Whitening Gel (March 2000), Aquafresh Whitening Toothpaste (April 2000), Colgate Total Plus Whitening Toothpaste (June 2000), Rembrandt Whitening Toothpaste (October 2000)

**Manufacturers:** Crest—Procter & Gamble, P.O. Box 599, Cincinnati, Ohio 45201-0599, 1-800-492-7378, “www.pg.com”; Colgate—Colgate-Palmolive Company, 300 Park Ave., New York, N.Y. 10022, 1-800-468-6502, “www.colgate.com”; Aquafresh—GlaxoSmithKline, P.O. Box 1467, Pittsburgh, Pa. 15230, 1-800-897-5623, “www.aquafresh.com”; Rembrandt—Den-Mat Corporation, 2727 Skyway Drive, Santa Maria, Calif. 93455, 1-800-433-6628, “www.rembrandt.com”

**Description:** Toothpastes typically contain abrasives (to remove debris and residual stain), humectants (to prevent loss of water), thickening agents or binders (to stabilize toothpaste formulations and prevent separation of liquid and solid phases), and flavoring and foaming agents (a preference of consumers). Therapeutic agents include fluoride (contained in all ADA-Accepted toothpastes for reducing caries), potassium nitrate (to treat dentinal hypersensitivity), and triclosan or stannous fluoride (to reduce gingival inflammation). Other agents that may be added to toothpastes to provide esthetic benefits are pyrophosphates or zinc citrate (to prevent tartar buildup) and various abrasives or enzymes (to help whiten teeth). Toothpastes that whiten teeth work by chemically or mechanically removing stain. The outcome is stain removal without damage to the underlying tooth structure. Whitening toothpastes that remove surface stain should not be confused with bleaching agents that work by breaking down pigment to remove color from teeth.



“(Product Name) is an “Accepted” HOME-USE TOOTH WHITENING MATERIAL when used according to the manufacturer’s instructions. Council on Scientific Affairs, American Dental Association

**Considerations for Acceptance:** The basis for review of all toothpastes submitted to the ADA Acceptance Program are the Guidelines for Fluoride-Containing Dentifrices. These guidelines detail the testing required to demonstrate that the dentifrice is safe and effectively prevents caries. In addition to this testing, whitening toothpastes are evaluated according to the ADA Acceptance Program Guidelines for Home-Use Tooth Whitening Products. Any other therapeutic claim attributed to whitening toothpastes also must be supported with studies (for example, claims for the reduction of plaque and gingivitis or hypersensitivity should be supported by studies consistent with ADA guidelines). ADA consultants review the testing results supplied by the toothpaste manufacturers.



**Efficacy Data:** Toothpaste manufacturers conduct extensive fluoride testing. This testing includes measurement of fluoride concentration, fluoride release in one minute (comparable to normal brushing habits) and incorporation of fluoride into enamel. The ADA laboratory conducts some fluoride testing as well. In addition to the fluoride data, two independent clinical studies must be conducted demonstrating the ability of the toothpaste to whiten teeth. The criteria for the clinical studies are double-blinding, study duration of six to eight weeks (with assessments pre-treatment, midtreatment and posttreatment), treatment and control groups (at least 25 subjects per group), assessments of at least four maxillary anterior teeth and color change measurements by either devices (such as colorimeters or spectrophotometers) or special color-matching scales (such as shade guides).

**Safety Data and Toxicity:** Whitening toothpastes submitted to the Acceptance program must complete the following evaluations demonstrating safety:

- measurement of enamel hardness to identify any damage to dental enamel and dentin with extreme use of the toothpaste;
- assessments of enamel morphology to identify any degradation of the enamel surface;
- testing to identify any effect of the whitener on restorative materials;
- toxicological assessments to identify cytotoxicity, mutagenicity and the potential for mucosal irritation.

In addition, periodontal health measurements must be made and any adverse events must be reported.

**Mechanism of Action:** The whitening ingredients in Crest and Colgate whitening toothpastes are special silica abrasives that prevent the formation of stains and remove stain from the tooth surface. The whitening ingredient in Aquafresh is sodium tripolyphosphate, a surfactant and chelator, that is effective against calcified stain. Rembrandt contains Citroxane, a patented formula that chemically disrupts stain through the combined action of papain, citrate and aluminum oxide. Papain is a proteolytic enzyme that is thought to whiten by dissolving the proteinaceous component of the stain. Citrate is added to enhance the activity of papain. Aluminum oxide is a mild abrasive. All these toothpastes whiten by removing stained pellicle on the tooth surface.

The Dental Product Spotlight appears in JADA each month to help dentists stay current on new products entering the marketplace and receiving the ADA Seal of Acceptance. These reports are prepared by the ADA Division of Science, in cooperation with The Journal of the American Dental Association. All rights reserved.

# Toothpaste formulation

**P**racticing good oral hygiene results in the reduction of plaque, caries and gingivitis. Toothpastes improve oral hygiene by enhancing the effect of mechanical scrubbing with a toothbrush and by delivering therapeutic agents to the oral cavity. The composition of toothpastes can be modified depending on the targeted therapy; however, the main therapeutic effect is a reduction of caries that occurs through assimilation of fluoride ions into the apatite crystal of enamel. Fluoride in toothpaste is in the form of sodium fluoride, stannous fluoride or sodium monofluorophosphate. In addition to their anticaries effect, most toothpastes can be broadly classified as having anti-tartar, cosmetic, antigingivitis, antiplaque or anti-hypersensitivity effects, or some combination of these effects.

## THE COMPONENTS OF TOOTHPASTE

**Abrasives.** Abrasives are added to toothpaste to remove stained pellicle from dentition. Abrasives work in concert with the toothbrush and have no effect on their own. The removal of plaque also is associated minimally with abrasives, which is another action attributed to the toothbrush. Calcium carbonate, dicalcium phosphates, hydrated alumina and various silica compounds are used as abrasives in toothpaste. The factors that affect the cleaning agent's abrasivity are hydration, particle size and shape, source, purity, and physical or chemical treatment. Ideally, abrasives should be nearly inert chemically. Toothpastes are tested to determine whether the abrasive component is satisfactory for removal of stain, while not damaging to the tooth structure.

**Detergents.** Detergents also are added to toothpastes for cleaning. Detergents act by lowering surface tension to solubilize substances, allowing penetration and loosening of surface deposits. The foaming action of toothpastes results from the addition of detergents. It is important that the detergent added to a toothpaste is mild so that it does not irritate the oral mucosa. The most commonly used detergent is sodium lauryl sulfate. There have been reports of sodium lauryl sulfate's causing increased oral irri-

tation in people who have recurring aphthous ulcers. For such people, manufacturers make toothpastes that do not contain sodium lauryl sulfate.

**Humectant systems.** Humectants and binding agents are important ingredients for maintaining the consistency of toothpaste. They are combined with preservatives to form complex mixtures referred to as humectant systems, which fulfill three purposes:

- providing a vehicle to which the other ingredients can be incorporated;
- keeping moisture in the toothpaste;
- preventing the growth of microorganisms.

The humectants commonly used are polyols (that is, glycerin, sorbitol and hydrogenated starch hydrolyzates). The preservative usually added is sodium benzoate. Binding agents are hydrophilic colloids that prevent separation of the toothpaste components by maintaining the liquid and solid components in one phase. A naturally occurring binding agent is gum arabic; synthetic ones include sodium carboxymethylcellulose and magnesium aluminum silicate.

**Flavoring agents.** Either natural flavoring agents (such as spearmint, peppermint, wintergreen, cinnamon, anise and fruit extracts) or artificial flavoring agents are added to toothpaste. ADA-Accepted toothpastes do not contain sugar, but some do contain artificial sweeteners (such as saccharin). The humectants glycerin and sorbitol also give toothpaste a sweet taste.

## FORMULATION: AN IMPORTANT CONSIDERATION

The combination of ingredients selected for a toothpaste depends on the desired qualities of the toothpaste and on the ingredients' compatibility. A toothpaste's formulation is an important consideration, because some ingredients can interfere with the effectiveness of others. For example, some cleaning agents have been shown to interfere with the availability of some therapeutic agents. The purity and chemical nature of the toothpaste ingredients, therefore, have become an important consideration. ■