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DENTIFRICE COMPOSITION CONTAINING ALUMINUM CHLORHYDROXY ALLANTOINATE

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ABSTRACT OF THE DISCLOSURE

A dentifrice composition effective in the treatment of the condition known as hypersensitive dentin and comprising aluminum chlorhydroxy allantoinate in a conventional dentifrice vehicle is disclosed.

This invention relates to an improved dentifrice composition for the treatment of persons having the condition known as hypersensitive dentin.

Hypersensitive dentin is a dental problem found in persons whose tooth surfaces are depleted because of erosion or chipping of the enamel or whose tooth dentin and cementum is exposed because of recession of the gingiva. The problem is prevalent among adults but children have been known to suffer as well. The condition exhibits itself as a painful sensation in response to ordinary stimuli at the surface of the teeth; high and low temperatures, changes in acidity, osmotic pressures, mechanical forces and certain foodstuffs will cause a painful sensation. The cause or causes of this condition are not known and are particularly obscure since calcified tooth structure does not contain nerve tissue. One theory widely accepted is that the dentinal tubules and odontoblastic fibrils in dentin, which normally produce calcified compounds in the tooth structure, are able to transmit impulses from the tooth structure to the dental pulp which does contain sensitive nerve endings. The dentinal tubules and odontoblastic fibrins comprise a substantial portion of the organic fraction of tooth dentin and this explains the greater sensitivity of exposed dentin.

A number of agents have been used to treat hypersensitive dentin but most are not satisfactory for the reasons that they are toxic or otherwise so dangerous as to require professional administration. Other agents are unsatisfactory because they are reactive with other materials in dentifrice compositions or because they discolor the teeth or produce other undesirable side effects in the mouth. Agents which have met with limited success include solutions of sodium fluoride, sodium silicofluoride, formaldehyde, silver nitrate, zinc chloride and glycerine. U.S. Pat. No. 3,122,433 to Rosenthal describes dentifrice compositions including a solution of water-soluble ionic strontium compound in combination with a surface-active wetting agent. It is theorized that strontium ions are absorbed on the dentin in the tooth structure thereby insulating the sensitive dental pulp from the exterior surfaces of the teeth. The other components of the dentifrice composition must be non-reactive with the strontium compounds used and only those strontium compounds which exhibit a substantial solubility in the amounts of water present in dentifrice compositions can be employed.

The primary object of this invention is, therefore, to

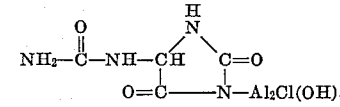
provide an improved dentrifrice agent suitable for treatment of persons having hypersensitive dentin and which can be included in a wide range of dentifrice compositions.

A related object of this invention is to provide dentifrice compositions having an agent which, while densensitizing hypersensitive dentin, is neither toxic nor dangerous to the user nor has undesirable side effects in the mouth.

It has been discovered that dentifrice compositions containing an effective amount of aluminum chlorhydroxy allantoinate are valuable in the treatment of hypersensitive dentin. The addition of this compound to any of a large number of dentifrice compositions provides an improved composition having soothing and pain relieving properties. For example, the topical application of a dentifrice composition encompassed by this invention causes the intense pain characteristic of hypersensitive dentin in response to hot and cold to disappear even after a very short period. Furthermore, dentifrice compositions containing aluminum chlorhydroxy allantoinate are stable and may be used at home without professional assistance.

It has been discovered that hypersensitive dentin can be substantially alleviated by administering to the teeth a composition comprised of a dentifrice vehicle and an effective amount of aluminum chlorhydroxy allantoinate, allowing the composition to contact the exposed sensitive areas of teeth manifesting hypersensitive dentin for a time sufficient to relieve the sensitivity, and repeating the procedure at intervals as necessary.

Aluminum chlorhydroxy allantoinate is a complex aluminum salt of allantoin, having the structural formula:



It may be formed from allantoin by the procedures taught in U.S. Pat. No. 2,761,867 to Mecca.

The aluminum chlorhydroxy allantoinate can be incorporated in the entire spectrum of dentifrice compositions including powders, pastes, rinses, wash-solutions, as well as lozenges, troches, chewing gums, and the like. The amount of allantoinate incorporated should be sufficient to provide relief to the sufferer. Broadly .01 to 10% by weight of the dentifrice composition can be aluminum chlorhydroxy allantoinate and best results are obtained if the dentifrice composition is 0.5 to .5% by weight aluminum chlorhydroxy allantoinate.

The dentifrice ingredients used to form the carriers or vehicles for the active agent of the invention are those conventionally used in dentifrice formulations. They include bodying or gelling agents such as the high molecular weight carbohydrate and cellulosic polymers, for example starches, methylcellulose, hydroxyethylcellulose and polyoxyethylene; inorganic chemical polishing agents of low solubility such as the phosphates, carbonates and sulfates of calcium and magnesium and micronized silica; surface active wetting or foaming agents consisting of longchain fatty acids or fatty alcohol derivatives, fatty acid soaps and fatty acids or alcohols etherified, esterified or condensed with sulfates, phosphates, amino acids, polyalkylene oxides or conjugated cyclic derivatives; pre-

servatives such as sodium benzoate, methyl parahydroxybenzoate and the like; humectants and smoothing agents such as glycerin and propylene glycol; coloring and perfuming agents; and a variety of materials having an antibiotic or therapeutic effect.

The following examples set forth a number of effective dentifrice compositions and demonstrate their usefulness in the treatment of hypersensitive dentin.

EXAMPLE I

A dentifrice paste having the following composition is prepared:

Ingredient:	Percent by weight
Hydral	40.00
Starch, Staley's Redried A	2.50
Glycerol	26.30
Water	23.565
Methylparabenzoate	0.08
Propylparabenzoate	0.02
Saccharin, soluble	0.15
PVP K–30 (polyvinylpyrollidone)	0.50
Sarkosyl NL–30	5.00
Mineral oil, light	0.50
Flavor #31538 (Fritzsche)	1.00
Aluminum chlorhydroxy allantoinate	0.20
Sodium chloride	0.172
Potassium chloride	0.006
Calcium chloride	0.007

The ingredients are first weighed. Water and glycerol are mixed and the PVP–30 and starch are added with stirring, the stirring being continued until the temperature of the mixture is 85–90° C. The mixture is then weighed to determine the water loss and that quantity of water is replaced. The methylparabenzoate, propylparabenzoate and soluble saccharin are then added and stirred into the mixture. The mixture is placed in a paste machine and the Hydral added slowly to it to avoid lumping, the resulting mixture being mixed for about ten minutes. The mineral oil is added next and the mixture is mixed for ten minutes more. Sarkosyl NL–30 and flavoring are next added and again the mixture is mixed for ten minutes. The aluminum chlorhydroxy allantoinate, sodium chloride, potassium chloride and calcium chloride are then added separately and after each addition the mixture is mixed for five minutes. The final mixture is mixed until a smooth paste results.

The paste is used in the treatment of persons having hypersensitive dentin. The paste is brushed in the mouth and allowed to thoroughly contact the teeth. After several minutes it is removed. In all cases the characteristic hot-cold sensitivity is substantially alleviated.

EXAMPLE II

A dentifrice paste having the following composition is prepared:

Ingredient:	Percent by weight
Water	40.0
Glycerin	28.0
Hydroxyethylcellulose	1.6
Polyoxyethylene sorbitan monolaurate	2.0
Micronized silica	27.0
Spearmint oil	1.0
Saccharin	0.2
Aluminum chlorhydroxy allantoinate	0.2
Total	100.0

The paste is used with success to treat persons having hypersensitive dentin.

The following dentifrices also are useful for the treatment of persons having hypersensitive dentin.

EXAMPLE III

Ingredient:	Percent by weight
Water	38.0
Calcium carbonate	20.2
Sodium N-lauryl N-methyltaurate	2.5
Sorbitol	21.0
Micronized silica	14.7
Methylcellulose	2.0
Peppermint oil	0.8
Dulcin	0.5
Aluminum chlorhydroxy allantoinate	0.3
Total	100.0

EXAMPLE IV

Ingredient:	Percent by weight
Water	30.00
Aluminum hydroxide	29.00
Micronized silica	11.85
Glycerin	24.00
Polyoxyethylene polymer (molecular weight about 2,000,000)	1.8
Polyoxyethylene lauryl ether	2.0
Spearmint oil	0.9
Methyl salicylate	0.1
Methyl parahydroxybenzoate	0.05
Saccharin	0.15
Aluminum chlorhydroxy allantoinate	0.15
Total	100.00

EXAMPLE V

Ingredient:	Percent by weight
Water	78.60
Micronized silica	14.00
Methylcellulose	2.35
Methyl parahydroxybenzoate	0.07
Propyl parahydroxybenzoate	0.03
Polyethylene sorbitan monostearate	0.30
Spearmint oil	0.70
Peppermint oil	0.30
Saccharin	0.30
Aluminum chlorohydroxy allantoinate	0.15
Total	100.00

EXAMPLE VI

Ingredient:	Percent by weight
Calcium carbonate	30.0
Tetra-oxyethylene sorbitan mono-oleate	0.5
Algin	1.0
Essential oils (for flavoring)	1.0
Propylene glycol	25.0
Alcohol	0.9
Water	41.4
Aluminum chlorhydroxy allantoinate	0.2
Total	100.0

EXAMPLE VII

A tooth powder having the following composition is prepared:

Ingredient:	Percent by weight
Sodium hexametaphosphate	34.90
Calcium carbonate	54.90
Gum tragacanth	9.00
Saccharin	0.10
Aluminum chlorhydroxy allantoinate	0.25
Oil of peppermint	0.85
Total	100.00

The powder is prepared by triturating the several ingredients which are in finely divided form until a uniform mixture is obtained. It is used with success to treat persons having hypersensitive dentin.

EXAMPLE VIII

A dental rinse or mouth wash having the following composition is prepared by methods known to the art:

Ingredient:	Percent by weight
Glycerine	12.00
Alcohol	5.00
Saccharin	0.10
Methol	0.01
Liquor amaranth	0.20
Sodium benzoate	0.10
Aluminum chlorohydroxy allantoinate	0.20
Distilled water	82.39
Total	100.00

The rinse is used with success to treat persons having hypersensitive dentin.

EXAMPLE IX

A lozenge is prepared having about 0.2% aluminum chlorhydroxy allantoinate from the following ingredients: extract of glycyrrhiza, powdered tragacanth, powdered sucrose, aluminum chlorhydroxy allantoinate and syrup of tolu.

The lozenges may be used effectively in the treatment of persons having hypersensitive dentin.

EXAMPLE X

Chewing gum having about 0.2% aluminum chlorhydroxy allantoinate is prepared from the following ingredients: Chicle, saccharin, flavoring, aluminum chlorhydroxy allantoinate.

The gum can be chewed by person having hypersensitive dentin with good results.

I claim:

1. A method for the treatment of persons suffering from the condition known as hypersensitive dentin comprising administering to the teeth a composition consisting essentially of a dentifrice vehicle and between about 0.1 to 10% by weight of aluminum chlorhydroxy allantoinate, and allowing the composition to contact the exposed sensitive areas of teeth manifesting hypersensitive dentin for a time sufficient to relieve the sensitivity.

2. The method of claim 1 wherein the composition is a paste containing from .05 to .5 percent by weight aluminum chlorhydroxy allantoinate.

References Cited

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RICHARD L. HUFF, Primary Examiner

U.S. Cl. X.R.

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