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(54) Title: ORTHODONTIC APPLIANCE SHIELD COMPOSITION

(57) Abstract: This invention relates to an orthodontic appliance shield composition adapted to be applied to an orthodontic appli-  
ance to protect the mouth tissue of a person wearing the orthodontic appliance. The shield is in the form of a polyvinyl acetate in a  
gel form. The gel has superior adhesive characteristics over traditional orthodontic wax products and thus remains in position for a  
relatively longer period of time than prior art wax products. The gel is further translucent and therefore not as noticeable as prior art  
mouth guards, plastic shields, caps, and wax products being applied to the orthodontic appliance.



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## ORTHODONTIC APPLIANCE SHIELD COMPOSITION

### INTRODUCTION AND BACKGROUND TO THE INVENTION

5 This invention relates to an orthodontic appliance shield composition.

The invention particularly relates to an orthodontic appliance shield, which is adapted to be applied to an orthodontic appliance between the appliance and the mouth tissue such as the cheeks, tongue or lips of a person wearing the  
10 orthodontic appliance. The orthodontic appliance may be a brace, brackets, or other dental work. The orthodontic appliance shield creates a shield or barrier between the orthodontic appliance and the mouth tissue, thus protecting and reducing irritation to the mouth tissue.

15 Known orthodontic appliance shields include mouth guards, orthodontic wax products, plastic shields, and caps, which fit over brackets of the braces.

Some of the disadvantages of mouth guards, plastic shields and caps are that they do not look aesthetically appealing and they are uncomfortable to wear  
20 since they are relatively bulky.

A known orthodontic wax product comprises a wax strip, from which a piece is broken off to be applied to the bracket.

Some of the disadvantages of such an orthodontic wax product are that the wax does not adhere to the bracket as such, since the wax is not an adhesive product and the wax is therefore relatively difficult to apply and locate.

5

Another disadvantage of the said orthodontic wax product is that once the wax is in position on the bracket, it easily falls off when hot food or drink is consumed by the person wearing it, since the wax melts.

- 10 Yet another disadvantage of the orthodontic wax product is that it does not look aesthetically appealing once applied to the brackets of a person's braces since the wax is relatively bulky and off-white in colour.

US patent 5,938,435 relates to an orthodontic appliance shield system  
15 comprising a strip of mesh gauze, which is impregnated and surrounded by wax. The strip envelops the raised portion of the appliance and covers the total length of the appliance. In use, a user cuts the strip to the desired length so as to envelop the brackets and wire of the appliance. The strip is placed in position and pressure is applied to the strip to manipulate it so that it wraps around the  
20 exterior of the brackets, thus engaging the brackets to be retained in position.

A first disadvantage of the above orthodontic appliance shield system is that, since the wax is not an adhesive product, pressure must be applied to the strip

so that it wraps around the brackets, thus making it relatively difficult to remove it completely from the brackets after use.

A second disadvantage of this system is that it does not look aesthetically appealing once applied to the brackets for the same reasons stated above.

A further disadvantage of the orthodontic appliance shield system is that, since the shield consists mainly of wax, the wax needs to be heated prior to application so that it becomes soft and pliable for application. Application of this shield is therefore tedious and time consuming.

Various forms of polyvinyl acetate as such are well known. A general disadvantage of most polyvinyl acetates is that it is relatively difficult to work with when in gel form, as it tends to clog up tubes and machinery.

15

### **OBJECT OF THE INVENTION**

It is therefore an object of the present invention to provide an orthodontic appliance shield composition with which the numerous aforesaid disadvantages of the prior art products can be overcome or at least minimised.

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### **SUMMARY OF THE INVENTION**

According to a first aspect of the invention there is provided an orthodontic appliance shield composition adapted to be applied to an orthodontic appliance

for protecting the mouth tissue of a person wearing the orthodontic appliance,  
the shield being in the form of a polyvinyl acetate in a gel form.

The composition may further include a solvent in the form of non-poisonous  
5 medicinal grade alcohol.

The medicinal grade alcohol may include ethanol.

Preferably the medicinal grade alcohol includes at least 96,5% pure ethanol.  
10

The polyvinyl acetate may constitute between 65% and 90%, preferably 73.8%  
of the composition on a mass per mass basis.

The alcohol may constitute between 10% and 35%, preferably 23.8% of the  
15 composition on a mass per mass basis.

The composition may further include a wetting agent.

The wetting agent may be glycerol triacetate.  
20

The wetting agent may constitute between 0.005% and 5%, preferably 0.2% of  
the composition on a mass per mass basis.

5

The gel may optionally include a flavouring agent.

The flavouring agent may constitute up to 15%, preferably 2.2% of the composition on a mass per mass basis.

5

The composition may further optionally include any one or more additives selected from the group consisting of a colouring agent, a topical anaesthetic, a fungicide, breath freshener, fluoride, teeth whitener, an anticoagulant to prevent bleeding, and an antibiotic.

10

The polyvinyl acetate may have a molecular weight of  $130 \times 10^3$  (in accordance with SEC, PS – Standard).

The polyvinyl acetate (10% in ethylacetate) may have a viscosity of 9,5 mPa.s (in accordance with DIN 53 015 at 20 °C).

15

Preferably the polyvinyl acetate is vinyl acetate homopolymer, CAS No. (9003-20-7) sold under the VINNAPAS® UW 1 fs trade mark by Wacker Polymer Systems GmbH & Co. KG, Johannes-Hess Strasse 24, D84489, Burghausen, Germany.

20

According to a second aspect of the invention there is provided a method of preparing an orthodontic appliance shield composition adapted to be applied to

an orthodontic appliance to protect the mouth tissue of a person wearing the orthodontic appliance, the method including the steps of providing a container; disposing a polyvinyl acetate in solid particulate form in the container; disposing a solvent in the container; closing the container; and forming a gel of the polyvinyl acetate by dissolving the polyvinyl acetate in the solvent whilst being disposed in the container.

The step of disposing the solvent in the container may include the further step of disposing a wetting agent in the container prior to the step of closing the container.

The method may include the further step of mixing the solvent and the wetting agent prior to disposing the same in the container.

15

The invention will now be described further by way of a non-limiting example.

#### **EXAMPLE**

An orthodontic appliance shield composition according to a preferred embodiment of the invention is prepared in accordance with a method including the steps of:

1. providing a closable container in the form of a tube having a volume of 14 g;
2. adding 10.33 g polyvinyl acetate to the tube;
- 5 3. mixing 3.33 g medicinal grade alcohol in the form of 96.5% pure ethanol with 0.03 g wetting agent, such as glycerol triacetate and 0.31 g flavouring agent such as spearmint flavour;
- 10 4. adding the mixture to the polyvinyl acetate in the tube;
5. sealing the tube;
6. mixing the mixture with the polyvinyl acetate in the tube; and
- 15 7. allowing the mixture to gel.

The method may include the further step of adding an additive selected from the group consisting of a colouring agent, a topical anaesthetic, a fungicide, a  
20 breath freshener, fluoride, a teeth whitener, an anticoagulant, and an antibiotic to the mixture prior to introducing the mixture to the tube.

The polyvinyl acetate (10% in ethylacetate) has a molecular weight of  $130 \times 10^3$  (in accordance with SEC, PS – Standard) and a viscosity of 9,5 mPa.s (in accordance with DIN 53 015 at 20 °C). The polyvinyl acetate is vinyl acetate homopolymer, CAS No. (9003-20-7) sold under the VINNAPAS® UW 1 fs trade  
5 mark by Wacker Polymer Systems GmbH & Co. KG, Johannes-Hess Strasse 24, D84489, Burghausen, Germany.

In applying the gel to an orthodontic appliance, such as to brackets of braces, a relatively small amount of gel is squeezed from the tube and applied to the  
10 brackets, so as to form a protective barrier between the brackets and the mouth tissue, such as the gums, lips and tongue, of the person wearing the braces.

It was found that the orthodontic appliance shield composition in accordance with the present invention has superior adhesive characteristics over traditional  
15 orthodontic wax products. For example, the composition is relatively easier to apply to the brackets and remains in position for a relatively longer period of time than prior art wax products.

A further advantage of the orthodontic appliance shield composition of the  
20 present invention is that if no colouring agent is added to the gel, the gel is translucent and therefore not as noticeable as prior art mouth guards, plastic shields, caps, and wax products being applied to the brackets. It is further

foreseen that the orthodontic appliance shield composition also protects the mouth tissue from broken teeth, or other irregular, pointed, or jagged surfaces.

It was also found that by preparing the composition inside the tube, the  
5 disadvantages experienced with the handling of polyvinyl acetate gels are overcome. Furthermore, by squeezing the gel from the tube and applying it to the brackets, relatively less handling of the gel is required, thus minimising contamination of the gel by germs on a person's hands. Use of the orthodontic appliance shield composition is therefore more hygienic than use of existing  
10 products.

It will be appreciated that variations in detail are possible with an orthodontic appliance shield composition according to the invention without departing from the scope of the appended claims.

**CLAIMS**

1. An orthodontic appliance shield composition to be applied to an orthodontic appliance for protecting the mouth tissue of a person wearing the orthodontic appliance, the shield being in the form of a polyvinyl acetate in a gel form.  
5
2. An orthodontic appliance shield composition according to claim 1 wherein the polyvinyl acetate constitutes between 65% and 90% of the composition on a mass per mass basis.  
10
3. An orthodontic appliance shield composition according to claim 2 wherein the polyvinyl acetate constitutes 73.8% of the composition on a mass per mass basis.  
15
4. An orthodontic appliance shield composition according to any one of the preceding claims which further includes a solvent in the form of non-poisonous medicinal grade alcohol.
- 20 5. An orthodontic appliance shield composition according to claim 4 wherein the medicinal grade alcohol includes ethanol.

6. An orthodontic appliance shield composition according to claim 5 wherein the medicinal grade alcohol includes at least 96,5% pure ethanol.
- 5 7. An orthodontic appliance shield composition according to any one of claims 4 to 6 wherein the alcohol constitutes between 10% and 35% of the composition on a mass per mass basis.
8. An orthodontic appliance shield composition according to claim 7  
10 wherein the alcohol constitutes 23.8% of the composition on a mass per mass basis.
9. An orthodontic appliance shield composition according to any one of the preceding claims which further includes a wetting agent.
- 15 10. An orthodontic appliance shield composition according to claim 9 wherein the wetting agent is glycerol triacetate.
11. An orthodontic appliance shield composition according to claim 10  
20 wherein the agent constitutes between 0.005% and 5% of the composition on a mass per mass basis.

12. An orthodontic appliance shield composition according to claim 11 wherein the agent constitutes 0.2% of the composition on a mass per mass basis.
- 5 13. An orthodontic appliance shield composition according to any one of the preceding claims which further includes a flavouring agent.
14. An orthodontic appliance shield composition according to claim 13 wherein the flavouring agent constitutes up to 15% the composition on a mass per mass basis.
- 10 15. An orthodontic appliance shield composition according to claim 14 wherein the flavouring agent constitutes 2.2% of the composition on a mass per mass basis.
- 15 16. An orthodontic appliance shield composition according to any one of the preceding claims which further includes any one or more additives selected from the group consisting of a colouring agent, a topical anaesthetic, a fungicide, breath freshener, fluoride, teeth whitener, an anticoagulant to prevent bleeding, and an antibiotic.
- 20

17. An orthodontic appliance shield composition according to any one of the preceding claims wherein the polyvinyl acetate has a molecular weight of  $130 \times 10^3$ .
- 5 18. An orthodontic appliance shield composition according to any one of the preceding claims wherein the polyvinyl acetate (10% in ethylacetate) has a viscosity of 9,5 mPa.s.
- 10 19. An orthodontic appliance shield composition according to any one of the preceding claims wherein the polyvinyl acetate is a vinyl acetate homopolymer.
- 15 20. A method of preparing an orthodontic appliance shield composition adapted to be applied to an orthodontic appliance to protect the mouth tissue of a person wearing the orthodontic appliance, the method including the steps of providing a container; disposing a polyvinyl acetate in solid particulate form in the container; disposing a solvent in the container; closing the container; and forming a gel of the polyvinyl acetate by dissolving the polyvinyl acetate in the solvent whilst being  
20 disposed in the container.

21. A method according to claim 20 wherein the step of disposing the solvent in the container includes the further step of disposing a wetting agent in the container prior to the step of closing the container.

5      22. A method according to claim 20 which includes the further step of mixing the solvent and the wetting agent prior to disposing the same in the container.

10      23. An orthodontic appliance shield composition substantially as herein described and exemplified.

24. A method of preparing an orthodontic appliance shield composition substantially as herein described and exemplified.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB2005/052697

**A. CLASSIFICATION OF SUBJECT MATTER**  
A61K6/00 A61K6/083 A61C7/12

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
A61K A61C G10D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  
EPO-Internal, WPI Data, PAJ, COMPENDEX, INSPEC, BIOSIS, EMBASE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 080 923 A (AUSTIN ET AL) 27 June 2000 (2000-06-27) column 3, line 23 - line 37 figures claims	1-24
A	PATENT ABSTRACTS OF JAPAN vol. 011, no. 369 (C-461), 2 December 1987 (1987-12-02) & JP 62 142112 A (LION CORP), 25 June 1987 (1987-06-25) abstract	1-24
A	US 5 938 435 A (RASPINO, JR. ET AL) 17 August 1999 (1999-08-17) cited in the application figures claims	1-24
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 4 559 013 A (AMSTUTZ ET AL)  17 December 1985 (1985-12-17)  figures  claims</p> <p>-----</p>	1-24

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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