

Technical Data Sheet

Product “OlivaFix Gold” Revolutionary denture Adhesive Cream
Class I

Comfort products

Version History			
Version	Date	Comments	Authors
01	07.11.2017	NEW TDS	SA/BJ
02	15.11.2018	Updated box – New reference of IFU	SA



Contents

1. General Information	3
2. Regulatory & Legal aspects.....	4
3. Production	4
4. Packaging	4
5. Quality control	4
6. References.....	5

1. General Information

Article No.	44.900.00.X.0.0.00	
Commercial name	“OlivaFix Gold” Revolutionary denture Adhesive Cream	
Brands	OlivaFix Gold	
Description	<p>The OlivaFix Gold Revolutionary Denture Adhesive Cream is the latest unique and innovative product developed and manufactured by bonyf AG.</p> <p>OlivaFix Gold is a one of a kind denture adhesive cream that combines a long hold of up to 24 hours and a healthy approach.</p> <p>OlivaFix Gold is free from zinc, mineral oils and petrolatum which are replaced by almost 35% of organic (BIO) extra virgin olive oil.</p> <p>Thanks to the Bio (Organic) Extra Virgin olive oil included in its formula, this product is designed to provide users a healthy approach and a safe product rich in antioxidants and nutritional benefits. The presence of phenolic compounds which are known by their antimicrobial and antioxidant activities, confers the same characteristics to this product. OlivaFix Gold is also considered as a source of vitamins such as Vitamins E & D and provitamin A.</p> <p>The main ingredients of OlivaFix Gold are also calcium-sodium PVM/MA copolymer and cellulose gum. These swelling materials create with saliva an elastic cushion between the denture and the mucosa. OlivaFix Gold grants a neutral taste, a silky smooth sensation and a day and night hold without any pasty feeling. One single application is enough for an optimal and comfortable hold. The cream acts also as anti-food particles and protects against pressure sores and irritation of the gums.</p>	
Use, Toxicity & safety	<p>The main difference between OlivaFix Gold and Regular, is that OlivaFix Gold includes the Organic Extra Virgin Olive oil which makes this variant healthier than the Regular OlivaFix which includes the refined olive on its formula.</p> <p>Biocompatibility tests of Regular OlivaFix were performed according to the ISO 10993-1 for biological evaluation of medical devices within a risk management process in conjunction with EN ISO 7405:2013 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.</p> <p>The tests of biocompatibility such as cytotoxicity, irritation and sensitization were conducted according to the ISO10993-5 and ISO 10993-10 on reconstructed human gingival tissues (10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity and 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization). (1)</p> <p>Results showed that OlivaFix Regular didn't induce any cytotoxic, irritant and sensitizing effects. With reference to these finding and due to the presence of organic extra virgin olive oil known as high source of nutrients, it is concluded that OlivaFix Gold is safe and did not present any risk to the health when applied according to the instructions for use. Safety evaluation was performed on 20 healthy subjects (by Dermatest). Results showed that OlivaFix Gold did not induce any undesired or even pathological skin reactions due to any skin irritant characteristics of the product. (2)</p>	
Composition/Indication	Chemical names	CAS No.
	Cellulose Gum	9004-32-4
	Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin)	8001-25-0
	Calcium/Sodium PVM/MA Copolymer	62386-95-2
	Hydrogenated soybean oil	8016-70-4
	Trihydroxystearin	8001-78-3
	Silica	68611-44-9 / 112945-52-5
	Menthol	2216-51-5
	Lecithin	8002-43-5
	Citrus Limon Peel Oil	8008-56-8
	Menthyl Lactate	59259-38-0

	CAUTION: Do not use product if tube nozzle is unsealed. Use the product according to instructions for use. Keep out of the reach of children. Do not use if there is a known sensitivity or allergy to one of the ingredients. If you are taking medication that may affect your gums or oral cavity, consult a dentist before using the product. In the event of gum irritation or soreness, discontinue use and consult your dentist if necessary. Pain and discomfort of the gums can also be caused by ill-fitting or broken dentures therefore it is important to consult your dentist on a regular basis. Store dry and at room temperature.
Shelf life	3 Years

2. Regulatory & Legal aspects

Classification Europe	Medical Device Class I
Classification process	Classification according to Annex IX of Directive 93/42/EEC The device is used in the oral cavity with one single application lasting up to 1 day approximately (24 hours). The device is always used in conjunction with a removable dental appliance. According to Rule 5 of Annex IX of the directive 93/42/EEC the product falls under a Class I device classification. With respect to the duration of use, for hygiene purposes and simply to do the nature of the device, the denture cream is reapplied following each use.
NBOG-Code	MD 0402 Dental materials
Target Audience	For wearers of full & partial removable dentures, metal or acrylic dentures.

3. Production


Hygiene during manufacturing process	Hairnet Gloves Shoe covers Breathing mask Disinfectants Laboratory clothing Ref: SOP 165-Hygiene
---	--

4. Packaging

Size/Quantities	OlivaFix Gold revolutionary Denture Fixative Cream – 75g Tube
Packaging of actual product	Plastic Tubes
External packaging	Pre-printed cardboard
Instructions for use	Included in the box (Article Nr. 44.700.09.T.0.0.100- R12112018D-PT)
Packaging Languages	Standard Language: English, French and German Other languages available on request
Storage	Store dry and at room temperature. Do not expose the tube to sources of heat or direct sunlight.
Delivery	6 weeks after initial order

5. Quality control

Properties	Specifications	Methods
Appearance	Homogeneous Paste; Light beige	Visual Inspection
Net Weight	(40 ± 1) g	Balance
Fmax : Bond Strength	No less than 7.6N	See ¹⁾
Shelf-life	3 years	See ²⁾

	“OlivaFix Gold” Revolutionary denture Adhesive Cream Technical Data Sheet	Technical document A2
Version Number: 02	Version Date: 15.11.2018	Article Number: 44.900.00.X.0.0.00
		Authors: AS/BJ

pH	Between 4 and 10	See ³⁾
-----------	------------------	-------------------

- 1) EN ISO 10873 : 7.5 Adhesion strength test I (for Type 1 adhesives) 7.6 Adhesion strength test II (for Type 1 adhesives)
- 2) See Stability Report Document
- 3) EN ISO 10873 : 7.2 pH value measurement

6. References

Additional Technical Information	Material Safety Data Sheet Declaration of Conformity
Scientific References	<ol style="list-style-type: none"> 1. Biocompatibility evaluation of OlivaFix: cytotoxicity, irritation and sensitization assays on Sterlab reconstructed human gingival tissue. Sterlab 2013. 2. OlivaFix GOLD- Dermatological expertise on a clinical-dermatological application test with subsequent questionnaire. Dermatest 2017.