

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



Version Number: 02 Version Date: 15.11.2018

Article Number: 44.900.00.X.0.0.00

Authors: AS/BJ

Contents

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



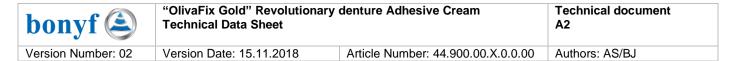
"OlivaFix Gold" Revolutionary denture Adhesive Cream Technical Data Sheet

Technical document A2

Version Number: 02 Version Date: 15.11.2018 Article Number: 44.900.00.X.0.0.00 Authors: AS/BJ

1. General Information

Article No.	44.900.00.X.0.0.00	
Commercial name	"OlivaFix Gold" Revolutionary denture Adhesive (Cream
Brands	OlivaFix Gold	
Brands Description		Cream is the latest unique and onyf AG. eam that combines a long hold of atum which are replaced by almost uded in its formula, this product is a safe product rich in antioxidants apounds which are known by their me characteristics to this product. In such as Vitamins E & D and an elastic cushion between a neutral taste, a silky smooth of feeling. One single application is am acts also as anti-food particles
Use, Toxicity & safety	The main difference between OlivaFix Gold and Regulate Organic Extra Virgin Olive oil which makes this wolivaFix which includes the refined olive on its formula Biocompatibility tests of Regular OlivaFix were perfor 1 for biological evaluation of medical devices within conjunction with EN ISO 7405:2013 Dentistry – Evaluate devices used in dentistry. The tests of biocompatibility such as cytotoxicity, conducted according to the ISO10993-5 and ISO 10 gingival tissues (10993-5:2009 Biological evaluation of for in vitro cytotoxicity and 10993-10:2010 Biological Part 10: Tests for irritation and skin sensitization). (1) Results showed that OlivaFix Regular didn't induce an effects. With reference to these finding and due to the olive oil known as high source of nutrients, it is concluded not present any risk to the health when applied according to the olivaFix Gold did not induce any und	variant healthier than the Regular a. med according to the ISO 10993- n a risk management process in ation of biocompatibility of medical irritation and sensitization were 10993-10 on reconstructed human of medical devices Part 5: Tests evaluation of medical devices reversely cytotoxic, irritant and sensitizing the presence of organic extra virgin ded that OlivaFix Gold is safe and cording to the instructions for use.
	reactions due to any skin irritant characteristics of the	•
Opposition for the con-	reactions due to any skin irritant characteristics of the	product. (2)
Composition/Indicatio	-	· · · · · · · · · · · · · · · · · · ·
Composition/Indicatio	reactions due to any skin irritant characteristics of the	product. (2)
•	reactions due to any skin irritant characteristics of the Chemical names	product. (2)
-	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra	CAS No. 9004-32-4
-	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin)	CAS No. 9004-32-4
-	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin) Calcium/Sodium PVM/MA Copolymer	CAS No. 9004-32-4 8001-25-0 62386-95-2
•	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin) Calcium/Sodium PVM/MA Copolymer Hydrogenated soybean oil	CAS No. 9004-32-4 8001-25-0 62386-95-2 8016-70-4
•	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin) Calcium/Sodium PVM/MA Copolymer Hydrogenated soybean oil Trihydroxystearin Silica	CAS No. 9004-32-4 8001-25-0 62386-95-2 8016-70-4 8001-78-3 68611-44-9 / 112945-52-5
•	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin) Calcium/Sodium PVM/MA Copolymer Hydrogenated soybean oil Trihydroxystearin Silica Menthol	CAS No. 9004-32-4 8001-25-0 62386-95-2 8016-70-4 8001-78-3 68611-44-9 / 112945-52-5 2216-51-5
-	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin) Calcium/Sodium PVM/MA Copolymer Hydrogenated soybean oil Trihydroxystearin Silica Menthol Lecithin	CAS No. 9004-32-4 8001-25-0 62386-95-2 8016-70-4 8001-78-3 68611-44-9 / 112945-52-5 2216-51-5 8002-43-5
-	reactions due to any skin irritant characteristics of the Chemical names Cellulose Gum Olea Europaea (Olive Fruit) Oil (Organic Extra Virgin) Calcium/Sodium PVM/MA Copolymer Hydrogenated soybean oil Trihydroxystearin Silica Menthol	CAS No. 9004-32-4 8001-25-0 62386-95-2 8016-70-4 8001-78-3 68611-44-9 / 112945-52-5 2216-51-5



	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

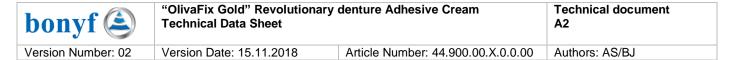
Hygiene during	Hairnet
manufacturing process	Gloves
	Shoe covers
	Breathing mask
	Disinfectants
	Laboratory clothing
	Ref: SOP 165-Hygiene

4. Packaging

Size/Quantities	OlivaFix Gold revolutionary Denture Fixative Cream – 75g Tube
Packaging of actual	Plastic Tubes
product	
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⁾



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

- 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 EN ISO 10873 : **7.2 pH value measurement**

6. References

Additional Technical Information	Material Safety Data Sheet Declaration of Conformity
Scientific References	 Biocompatibility evaluation of OlivaFix: cytotoxicity, irritation and sensitization assays on Sterlab reconstructed human gingival tissue. Sterlab 2013. OlivaFix GOLD- Dermatological expertise on a clinical-dermatological application test with subsequent questionnaire. Dermatest 2017.