	Technical Data Sheet Denture Adhesive Cream Superior		Technical document A2
Version Number: 05	Version Date: 22/01/2018	Article Numbers: 5.040.00.X.0.0.00 (Classic) 5.040.00.X.0.1.00 (Fresh) 5.030.00.X.0.0.00 (Low cost) 5.090.00.X.0.0.00 (23%)	Authors: SS/Myriam Z.

Technical Data Sheet


Product Denture Adhesive Cream Superior
Class I

Comfort products

Revision history:

Version	Date	Comments	Author
01	10.10.2011	Translation for German to English	SS
02	09.12.2013	TDs for different variants	SS
03	17.11.2015	Caution+ symbols (CLP regulation) + reference to instructions.	SS
04	30.11.2017	Adding the article number part + adding the biocompatibility part + updating brands + Caution + symbols (umbrella) + reference to the updated version of instructions + adding material specifications of the tube + adding the consistency specifications in the quality control section	Myriam Z.
05	22.01.2018	Adding article numbers for each variant + 75g in the size quantities section	Myriam Z.




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1. GENERAL INFORMATION

Article No.	5.040.00.X.0.0.00 (Classic) 5.040.00.X.0.1.00 (Fresh) 5.030.00.X.0.0.00 (Low cost) 5.090.00.X.0.0.00 (23%)
Commercial name	Denture adhesive Cream Superior
Brands	BonyPlus, Smile with Confidence, Professional
Description	<p>The Denture Adhesive Cream Superior is no ordinary denture adhesive. Its advanced formula reacts with moisture in the mouth to provide a super strong hold lasting for up to 12 hours. The fresh ingredients also prevent denture odour. The smooth and soft cream provides a comfortable sealed layer between the denture and the gums.</p>
Use, Toxicity & safety	<p>This product is easy to use for elderly people. No new application techniques need to be considered. All ingredients contained in the cream are safe to use. The product's formulation consists of the same basic ingredients as those of the major brands. The mode of action can also be compared to the major brands on the market. However, some differences are noted in the effectiveness (ie. hold and strength) of the product. It can therefore be concluded that if the product is applied according to the instructions there is no health risk by the daily use of the adhesive cream. Even in the case of unexpected misuse or swallowing of small amounts, the potential health risk is minimal.</p> <p>The Denture Adhesive Cream Superior is a Zinc-free formulation.</p> <p>Biocompatibility tests of Superior 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. 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). (3)</p> <p>Results showed that Superior didn't induce any cytotoxic, irritant and sensitizing effects. With reference to these findings and based on the PVM/MA ingredient that well known in the dentistry field for non-cytotoxic effect and also for the common use of menthol of denture adhesives on the market, it is concluded that Superior is safe and did not present any risk to the health when applied according to the instructions for use.</p> <p>Safety evaluation was performed on 20 healthy subjects (by Dermatest). Results showed that Superior did not induce any undesired or even pathological skin reactions due to any skin irritant characteristics of the product. (4)</p>

Composition/Indication	INCI Name	CAS No.
	Cellulose Gum	9004-32-4
	Petrolatum	8009-03-8
	Paraffinum Liquidum	8042-47-5
	Calcium/Sodium PVM/MA Copolymer	62386-95-2
	Silica	68611-44-9
	Silica	112945-52-5
	Menthol	2216-51-5




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	Menthyl Lactate	59259-38-0
	Lecithin	8002-43-5
Shelf life:	3 years	

2. REGULATORY AND LEGAL ASPECTS

Classification Europe	Medical Device Class I
Classification Process	Class I; as per Rule 5 of Annex IX of the directive 93/42/EEC.
NBOG- Code	MD 0402 Dental Materials
Target Audience	For wearers of full & partial removable dentures, metal or acrylic dentures. Not intended for use on children.

3. PRODUCTION

Hygiene	Hairnet Gloves Shoe covers Breathing mask Disinfectants Laboratory Clothing (REF : SOP165- Hygiene)	
Components	1 Tube of Adhesive Cream	
Machinery	Brand	Purpose
	Tonazzi	Tube Filling Machine
	Rigao	Packaging machine
Packaging	Tubes contained in carton boxes	
Size/Quantities	75g-70g-40g-20g-10g tube / 2,5 g Sachet	
Material of tube	Tube Body – Huhtamaki 2327FC/Amcor ABL275/12 Tube Shoulder – HDPE Liten MB 47 Tube Cap – Polypropylene Mosten GB003 Membrane (Top Seal) – top seal laminate Huhtamaki ALU40/PE32	
External packaging	Pre-printed cardboard	
Instructions for use	Instruction sheet is printed on the box. Article Nr. 5.545.00.A.0.0.44 (R15122016D-PT) 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.	
	  	
Labelling	All languages available on request	
Storage	Standard storage conditions – Cool & dry (<25°C)	
Delivery	6 Weeks after initial order	

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4. QUALITY CONTROL

Properties	Specification / Method (Masterfile E)
Appearance	Homogeneous Paste; Light beige
Net Weight	(40 ± 1) g
Fmax : Bond Strength	No less than 7.6N
Consistency	41-51mm
Shelf-life	3 years
pH	Between 4 and 10

5. REFERENCES

Additional Technical Information	<ol style="list-style-type: none"> Safety Data Sheet Declaration of Conformity Biocompatibility evaluation of Superior: cytotoxicity, irritation and sensitization assays on Sterlab reconstructed human gingival tissue. Sterlab 2012 Superior - Dermatological expertise on a clinical-dermatological application test with subsequent questionnaire. Dermatest 2014-2016 & 2017.
Scientific References	<ol style="list-style-type: none"> Floystrand F, Koppang R, Williams VD, Orstavik J: A method for testing denture adhesives. J Prosthet Dent 66 (1991) 501-504 Koppang R, Berg Em Dahm S, Floystrand F: A method for testing denture adhesives. J Prosthet Dent 73 (1995) 486-491 Jagger DC, Harrison A: Denture Fixatives – an update for general dental practice. British Dental Journal, Vol 180, No. 8 (April 1996) 311-313 Sterlab. Biocompatibility evaluation of Adhesive Cream Superior With Cytotoxicity, Irritation And Sensitization Assay On Sterlab Reconstructed Gingival Tissue, Vallauris. 2013. Dermatest application report.