

# BIORESISTENT PMU COLOR TECHNICAL DATA SHEET

*(Excerpt from the full version BioResistent Product Dossier)*

## INTRODUCTION

*This product is a color-based pigment intended for PMU, aesthetic corrective permanent make up, tattooing, micropigmentation, permanent make up. Intended for professional use only and to be used only by operators in possession of appropriate qualifications for the performance of specific tasks. It is not to be considered a medical surgical product within the meaning of Dir 93/42 EEC.*

*This certification is prepared in summary form, to respond to numerous requests for clarification expressed by the authorities in relation to the colors for PMU and Tattoo and is related to the following SET1/SET 2/SET3 of the BIORRESISTENT DERMOPIGMENTATION COLOR / COLOR PMU product.*

## STATEMENT

- 1- All colors in the range BioResistent (Set 1/Set 2/Set 3) comply with the regulations in force in Europe and outside Europe where the product has been placed on the market. In particular, responds to the suggestions made by the European Commission 20 February 2008, with the enactment of the European Resolution ResAP (2008)
- 2- All colors in the range BioResistent (Set 1/Set 2/Set 3), are free from carcinogenic aromatic amines covered by Annex 1 of the European Resolution ResAP (2008) 1 and expressed in detail in the tables 1/2/3 part integral ResAP (2008)<sup>1</sup> according to the method DIN EN ISO 14362-1
- 3- The colors of the range BioResistent (Set 1/Set 2/Set 3) do not use any dye prohibited and listed in Annex 2 of the European Resolution ResAP (2008)<sup>2</sup> as per test analysis TLC-HPLC - GC/MS by regulation DIN EN ISO 54231.
- 4- The heavy metals content in the range of colors BioResistent (Set 1/Set 2/Set 3) is in compliance with Appendix 3 of the European Resolution ResAP (2008)<sup>3</sup> following analysis system ICP-MS prescribed by regulation DIN EN ISO 11885.

<sup>1</sup> Table 1 List of aromatic amines, particularly with regard to their carcinogenic, mutagenic, reprotoxic and sensitising properties, which should neither be present in tattoos and PMU products nor released from azo-colorants

<sup>2</sup> Table 2 Non-exhaustive list of substances, particularly with regard to their carcinogenic, mutagenic, reprotoxic and/or sensitising properties, which tattoo and PMU products should not contain (BC/CEN/97/29.11)

<sup>3</sup> Table 3 Maximum allowed concentrations of impurities in products for tattoos and PMU

- 5- The pigments used for the preparation of the colors of the line BioResistent (Set 1/Set 2/Set 3) are for cosmetic and / or food and are not toxic at the doses used in the PMU.
- 6- Further compliance: Directive 93/35/EEC- ResAP(2003)2 and subsequent ResAP(2008)1  
Approval of Spanish Ministry A.M.P.S. PE n° 279/280/281  
Tattoo und PMU Verordnung Germany 2008  
Regulation (EC) on Cosmetic Products EC1223/2009  
REACH Regulation 1907/2006/CE  
European Cosmetics Directive 76/768/EEC and subsequent amendments  
DL.126  
Notified at the European portal CPNP(Cosmetic Products Notification Portal) <sup>4</sup>

PRODUCT CATEGORIES AND SUBDIVISION IN SET				
The colors of the range BioResistent are available in over 140 shades of color. Belong to these categories (SET) the following colors:				
BIORESISTENT SET 1				
401 BIOLIP 1	437 BLOND 1	451 BRUN 1	517 COLD GREY	468 SKIN 10
403 BIOLIP 3	438 BLOND 2	452 BRUN 2	431 WHITE	469 SKIN 11
404 BIOLIP 4	439 BLOND 3	453 BRUN 3	428 COVEREDWHITE	470 SKIN 12
406 BIOLIP 6	440 BLOND 4	454 BRUN 4	432 YELLOW	471 SKIN 13
407 BIOLIP 7	441 BLOND 5	455 WARM GREY	434 MINERAL RED	472 SKIN 14
410 BIOLIP 10	442 BLOND 6	502 BRUN 5	512 GREEN	473 SKIN 15
413 BIOLIP 13	443 BLOND 7		429 CORRECTOR 1	474 SKIN 16
414 BIOLIP 14	444 BLOND 8	329 DEEP BROWN	430 CORRECTOR 2	483 SKIN 17
419 BIOLIP 19	500 BLOND 9	330 GOLDEN BRONZE	436 BLACK	484 SKIN 18
421 BIOLIP 21	501 BLOND 10	331 COFFEE		485 SKIN 19
422 BIOLIP 22	445 BROWN 1	332 CHOCOLATE	459 SKIN 1	486 SKIN 20
477 BIOLIP 30	446 BROWN 2	338 OLIVE	460 SKIN 2	487 SKIN 21
478 BIOLIP 31	447 BROWN 3	340 MIDNIGHT	461 SKIN 3	488 SKIN 22
498 BIOLIP 39	448 BROWN 4	342 BRUNETTE	462 SKIN 4	489 SKIN 23
499 BIOLIP 40	449 BROWN 5		463 SKIN 5	490 SKIN 24
	450 BROWN 6	532 ARABICA	464 SKIN 6	510 SKIN 25
325 TRICO Corrector	491 BROWN 7	533 TERRE	465 SKIN 7	511 SKIN 26
326 TRICO Blond	503 BROWN 8	534 OCRA	466 SKIN 8	513 SKIN 27
327 TRICO Brown		535 BROWNIE	467 SKIN 9	514 SKIN 28
328 TRICO Brun		536 BRONZE		515 SKIN 29
		537 CAMEL		516 SKIN 30
BIORESISTENT SET 2				
408 BIOLIP 8	425 BIOLIP 25	496 BIOLIP 37	521 SUNSET	333 PURE RED
409 BIOLIP 9	426 BIOLIP 26	497 BIOLIP 38	522 KISS KISS	334 STRAWBERRY
411 BIOLIP 11	427 BIOLIP 27	506 BIOLIP 41	523 ORANGE RED	335 ANTIQUE ROSE
412 BIOLIP 12	475 BIOLIP 28	507 BIOLIP 42	524 GLAM	336 MAGIC PINK
415 BIOLIP 15	476 BIOLIP 29	508 BIOLIP 43	525 EXTREME	337 TANGERINE
416 BIOLIP 16	479 BIOLIP 32	435 BRIGHT RED	526 BABY ROSE	339 MYSTIC PURPLE
420 BIOLIP 20	480 BIOLIP 33	433 ORANGE	527 MARYLIN	341 SAFARI
423 BIOLIP 23	481 BIOLIP 34		528 HOT PINK	
424 BIOLIP 24	482 BIOLIP 35		529 FLIRT	
	495 BIOLIP 36		530 VIP PINK	
BIORESISTENT SET 3				
456 BLACK LINER		492 BROWN LINER		
538 POWER BLACK		493 BLUE LINER		
509 VIOLET LINER		494 GREEN LINER		

<sup>4</sup> CPNP Reference SET 1 1416219//2523417 - CPNP Reference SET 2 1416317 - CPNP Reference SET 3 1416284

BIORESISTENT PMU COLOR TECHNICAL DATA SHEET - Excerpt full version BioResistent product dossier by BIOTEK srl Via Strambio 26 Milano Italy T +39.02.7380144/5 F +39.02.7380147 security@biotek.it		
VERSION 7.0 - REVISION DATE 01.12.2017	PRINTING DATE 01.12.2017	PAG.:2/4
©2017 Biotek srl - Tutti i diritti riservati. All rights reserved.		

## COMPOSITION SPECIFICATIONS

### 1\_ LIQUID FRACTION - DILUENT

Glycerin - Isopropyl Alcohol - Aqua - Propylene Glycol - Ricin Oil - Polysorbate 20 - PVP  
Magnesium Aluminium Silicate - Aloe Barbadensis - Hamamelis Virginiana

### 2\_ SOLID FRACTION

#### Pigments used in SET 1

Iron Oxides (C.I. 77499, 77491,77492), Titanium Dioxide (C.I. 77891), Chromium Oxide Green (C.I. 77288)

#### Pigments used in SET 2

Iron Oxides (C.I. 77499, 77491,77492), Titanium Dioxide (C.I. 77891), Red 7 (C.I. 15850), Red 254 (C.I. 56110), Red 242 (C.I. 20067), Violet 517 (C.I. 12517)

#### Pigments used in SET 3

Black 2 (C.I. 77266), Ultramarines (C.I. 77007), Manganese Violet (C.I. 77742),  
Chromium Hydroxide Green (C.I. 77289), Iron Oxides (C.I. 77499, 77491,77492)

## STERILITY

Sterilization of pigment by irradiation of accelerated electrons.  
25 kGy dose performed by Gammatom - Italy  
Sterile according to Oxidase test as per ResAP (2008) 1, only for unopened and sealed bottle.

## BIOLOGY

### Bacteriologically pure product according to the metoto FUX Ed

Pseudomonas Aeruginosa	<i>absent</i>	Escherichia Coli	<i>absent</i>
Staphylococcus Aureus	<i>absent</i>	Coliformi	<i>absent</i>
Candida Albicans	<i>absent</i>		

## AROMATIC AMINE

### Product free of aromatic amines. Contents conform to the specifications ResAP (2008) 1

substance	ppm	substance	ppm
6-amino-2-ethoxynaphthaline	assente	3,3'-dimethoxybenzidine	assente
4-amino-3-fluorophenol	assente	3,3'-dimethylbenzidine	assente
4-aminoazobenzene	assente	6-methoxy-m-toluidine	assente
o-aminoazotoluene	assente	4-methoxy-m-phenylenediamine	assente
o-anisidine	assente	4,4'-methylenebis(2-chloroaniline)	assente
Benzidine	assente	4,4'-methylenedianiline	assente
Biphenyl-4-ylamine	assente	4,4'-methylenedi-o-toluidine	assente
4-chloroaniline	assente	4-methyl-m-phenylenediamine	assente
4-chloro-o-toluidine	assente	2-naphtylamine	assente
3,3'-d-dichlorobenzidine	assente	5-nitro-o-toluidine	assente

## PACKAGING

The product is supplied in packs tested with anti-opening warranty seal and airless system.  
The packages are offered in the sizes: 12mle./10mle and single-dose 2mle./ 5 mle.

## PRODUCT LIFE

5 years in sealed and intact bottle, stored at temperature from 10 ° C to 35 ° C  
See the expiration date and Period After Opening (PAO) printed on the package.

## CLINICAL TESTS

In support of product quality and safety, clinical tests have been carried out in-depth, well above the requirements of the regulations, at the Farcoderm and Farcos laboratories of the University of Pavia.

**BIORESISTENT PMU COLOR TECHNICAL DATA SHEET - Excerpt full version BioResistent product dossier**  
by BIOTEK srl Via Strambio 26 Milano Italy T +39.02.7380144/5 F +39.02.7380147 security@biotek.it

VERSION 7.0 - REVISION DATE 01.12.2017

PRINTING DATE 01.12.2017

PAG.:3/4

©2017 Biotek srl - Tutti i diritti riservati. All rights reserved.

Citotoxicity: NEGATIVE	Patch human test: NEGATIVE
Phototoxicity: NEGATIVE	Challenge test: NEGATIVE
Pro-sensitization: NEGATIVE	Microbiological: NEGATIVE
Eye irritation: NEGATIVE	Intradermal (Sp): NEGATIVE

### TEST CONCLUSIONS ON PRODUCTS

Conclusions on product:

NOT irritating	NOT carcinogen	NOT toxic
NOT immunotoxic	NOT mutagenic	NOT corrosive

### ACUTE TOXICITY

LD50, less than 10,000 times the lethal dose to 50% of rats.

### HAZARDS IDENTIFICATION

The product is not considered an hazardous substance. The product is without risk classification to health and the environment according to the current legislation .

*Adverse effects:* for the characteristics of the components, the preparation in case of proper use has no adverse effects except for any allergic reactions in particularly sensitive subject . The manufacturer recommends to perform hypoallergenic test of the color on the skin.

*Adverse effects to human health :* under normal conditions of use and in the form in which it occurs , the product has no harmful effects to human health.

*Contact with eyes:* due to the presence of alcohol, contact with eyes may cause temporary eye irritation.

*Contact with skin:* the product may cause irritation or allergic dermatitis on particularly sensitive people.

*Accidental Ingestion :* ingestion of significant amounts of product may cause nausea/vomiting.

*Inhalation :* in case of proper and normal use , there are no specific risks for inhalation.

*Adverse effects in the environment:* under normal conditions of use and in the form in which it presents , the product has no harmful to the environment. Substances classified as dangerous for the environment are absent in the formulation.

### PRODUCTION LABORATORY

Laboratorio Biotek s.r.l. Via Strambio, 26 Milano 20133 Italia in possession of:

- Clearance from Comune di Milano Settore Ambiente Energia
- Authorization of Comune di Milano Settore Ambiente Energia
- Clearance from ASL Milano Distretto 3
- Declaration of Hygienic Sanitary Conformity after Inspection by NAS

### SCIENTIFIC DIRECTOR

Dott. Dario Fatai (Chimico-Farmacologo)

### MANUFACTURING COMPANY

Produced in Italy by Biotek s.r.l.

ISO 9001 Certified Company since 2006

P.Iva 10911780152 - CCIAA 1418991

Phone +39 02.7380144/5 - Fax: +39 02.7380147 info@biotek.it www.biotek.it

### TECNICAL DOSSIER

BioResistent Product Dossier deepens what synthetically exposed in this certification.

Available for viewing only by authorities and following a written request.

Analysis performed by

Milan, 01.01.2017



UNIVERSITA' DEGLI STUDI DI PAVIA  
Dipartimento di Scienze  
Fisiologiche - Farmacologiche  
Cellulari - Molecolari



**BIOTEK srl**  
Dr Massimo Froio

**BIORESISTENT PMU COLOR TECHNICAL DATA SHEET - Excerpt full version BioResistent product dossier**  
by BIOTEK srl Via Strambio 26 Milano Italy T +39.02.7380144/5 F +39.02.7380147 security@biotek.it

VERSION 7.0 - REVISION DATE 01.12.2017

PRINTING DATE 01.12.2017

PAG.:4/4

©2017 Biotek srl - Tutti i diritti riservati. All rights reserved.