



# NEW REGULATION

TATTOO & PERMANENT MAKE-UP INKS

**WHAT YOU NEED TO KNOW  
TO WORK IN SAFETY**



# NEW REGULATION

## TATTOO & PERMANENT MAKE-UP INKS

REACH is the European Union Regulation developed to guarantee **the health and safety of people and the natural environment** the risks posed by a number of chemicals.

**R**egistration **E**valuation **A**uthorization and restriction of **CH**emicals

significa

**REGISTRAZIONE, VALUTAZIONE, AUTORIZZAZIONE  
E RESTRIZIONE DELLE SOSTANZE CHIMICHE.**



The European Regulation No. 1907/2006 (REACH)  
has been amended with a

## **INTEGRATION OF A NEW RESTRICTION RELATING TO INKS FOR TATTOOS AND PMU IN FORCE FROM 14.12.2020**

in agreement with

the Higher Institute of Health and Ministry of Health (REACH Competent Authority)



## POTENTIALLY DANGEROUS SUBSTANCES

The REACH Regulation limits the use and / or concentration of some substances considered dangerous within the inks / colors for tattooing and permanent make-up.





## **4,000 POTENTIALLY DANGEROUS SUBSTANCES**

The color implanted under the skin can release harmful substances  
in the long term defined:

CARCINOGEN    MUTAGENIC AND TOXIC FOR REPRODUCTION  
SENSITIZING / CORROSIVE / IRRITATING TO THE SKIN  
IRRITATING / HARMFUL TO THE EYES  
PROHIBITED IN COSMETIC PRODUCTS



# OBLIGATIONS OF THE MANUFACTURER

**COMPANIES MANUFACTURING COLOR FOR TATTOO AND PERMANENT MAKEUP**

**MUST ADAPT THEIR PRODUCTION WITHIN 4.01.2022**

The colors **ALLOWED** on the market are **ONLY** those compliant to the new regulation.





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IN or OUT

Based on the new production indications,  
**KNOWN AND POPULAR BRANDS**  
already on the market  
**ARE NO LONGER REGULAR**





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ATTENTION!

NOT ALL PIGMENTS ARE THE SAME

COMPLIANT TO EUROPEAN STANDARD  
100% SAFE and RELIABLE  
HYPOALLERGENIC  
NICKEL TESTED



NOT UNDER EUROPEAN STANDARD  
UNSAFE  
POTENTIALLY TOXIC  
POTENTIALLY CARCINOGENIC

# MORE THAN EVER



## NEW BIOTEK COLOR LINE

The new line of BIOTEK colors for PERMANENT MAKEUP & MICROBLADING has already been formulated in anticipation of the new REACH Regulation.





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## COMPLIANCE

NOT ALL PIGMENTS ARE EQUAL



THE NEW BIOTEK LINE  
**COMPLIES** WITH THE NEW  
EUROPEAN  
REGULATION





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## PROTOCOL OF BIOTEK PRODUCTION



### Security Rating Levels:

SEARCH OF ALLOWED RAW MATERIALS

CHEMICAL ANALYSIS OF PIGMENTS PRELIMINARY PHASE

CHEMICAL ANALYSIS OF PIGMENTS PRODUCTION PHASE

CLINICAL AND TOXICOLOGICAL TESTS

ISO 11137 STERILIZATION / VDmax25 method

STABILITY TESTS OF THE FINISHED PRODUCT

TRACEABILITY OF THE FINISHED PRODUCT





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## ANALYSES

RAW MATERIAL



BIOTEK TESTS ARE CARRIED OUT  
BY AUTHORITATIVE LABORATORIES



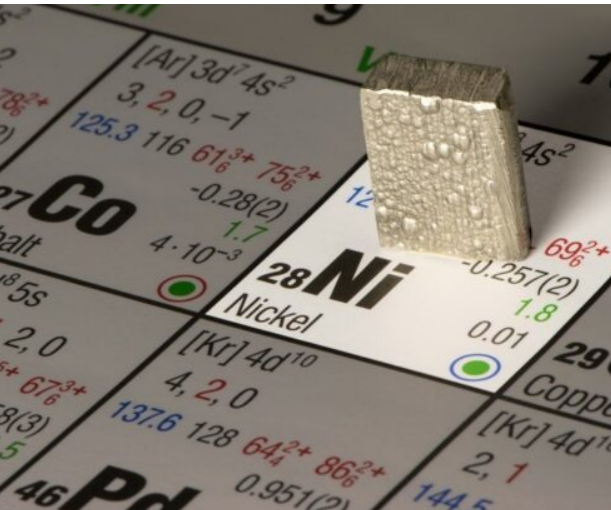




# NEW REGULATION

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## CONCENTRATION OF HEAVY METALS



THE NEW BIOTEK LINE  
**COMPLIES** WITH THE  
SPECIFIED LIMITS





# NEW REGULATION

## TATTOO & PERMANENT MAKE-UP INKS

# CONCENTRATION

# OF HEAVY METALS

Nome sostanza	Numero CE	Numero CAS	REACH Valore limite concentrazione peso %	REACH Valore limite concentrazione peso ppm	LOQ Limite quantificabile ppm
Mercurio	231-106-7	7439-97-6	0,00005 %	0,5	0,3
Nichel	231-111-4	7440-02-0	0,0005 %	5	0,3
Stagno organometallico	231-141-8	7440-31-5	0,00005 %	0,5	0,3
Antimonio	231-146-5	7440-36-0	0,00005 %	0,5	0,3
Arsenico	231-148-6	7440-38-2	0,00005 %	0,5	0,3
Bario **	231-149-1	7440-39-3	0,05 %	500	0,3
Cadmio	231-152-8	7440-43-9	0,00005 %	0,5	0,3
Cromo‡	231-157-5	7440-47-3	0,00005 %	0,5	0,02
Cobalto	231-158-0	7440-48-4	0,00005 %	0,5	0,3
Rame **	231-159-6	7440-50-8	0,025 %	250	0,3
Zinco **	231-175-3	7440-66-6	0,2 %	2.000	0,3
Piombo	231-100-4	7439-92-1	0,00007 %	0,7	0,3
Selenio	231-957-4	7782-49-2	0,0002 %	2	0,3



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CONCENTRATION  
**NICKEL**



REACH LIMIT

5ppm

<1ppm

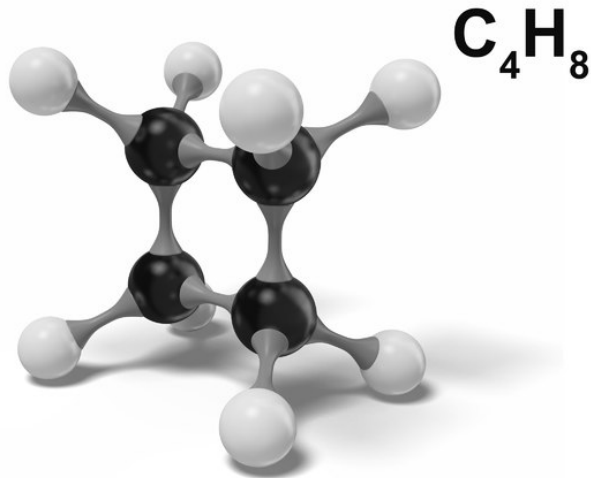


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CONCENTRATION

PAH - HYDROCARBONS



THE NEW BIOTEK LINE  
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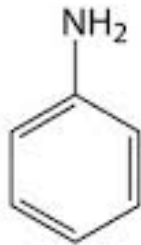
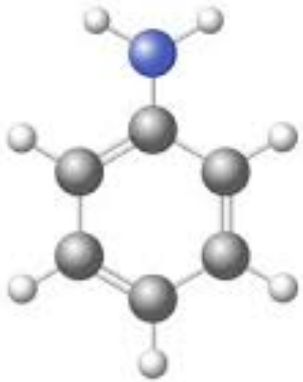


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## CONCENTRATION AROMATIC AMINES

Aniline



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## CONCENTRATION AZO DYES



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ANALYSES

FINAL PRODUCT



TOXICOLOGICAL ANALYSIS  
CITOXICITY





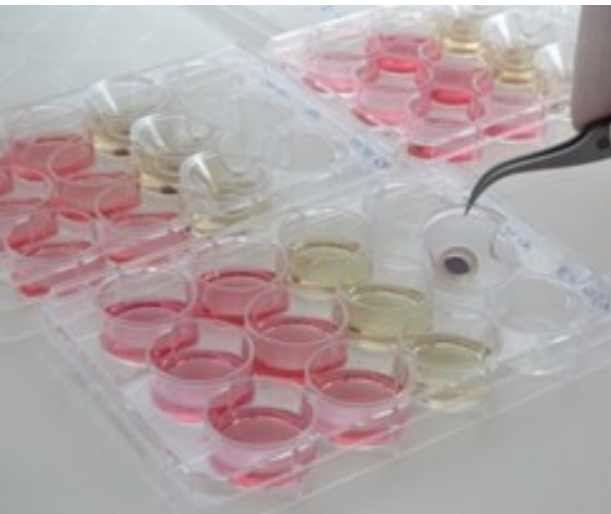


# NEW REGULATION

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ANALYSES

FINAL PRODUCT



BIOLOGICAL EVALUATION  
SKIN IRRITATION







# NEW REGULATION

TATTOO & PERMANENT MAKE-UP INKS

ANALYSES

FINAL PRODUCT



BIOLOGICAL EVALUATION  
INTRACUTANEOUS REACTION





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TATTOO & PERMANENT MAKE-UP INKS

ANALYSES

FINAL PRODUCT



POTENTIAL PHOTOTOXIC  
ASSESSMENT







# NEW REGULATION

## TATTOO & PERMANENT MAKE-UP INKS

# MSDS - DATA SAFETY SHEETS



### Scheda Dati di Sicurezza (MSDS)

Documento redatto secondo i Regolamenti (CE) n° 1907/2006 REACH e 453/2010

VERSION 02 REVISION DATE 01.02.2021

BIOTEK srl Via R. Farneo 8 20129 Milano Italy P.I. IT10911780152



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#### SEZIONE I - IDENTIFICAZI

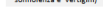
Nome commerciale  
Denominazione prodotto  
Codice prodotto  
Descrizione  
Produttore  
Contatto  
Utilizzo  
Contenuto  
NUMERO DI EMERGENZA

#### SEZIONE II - IDENTIFICAZI

CLASSE DI EMERGENZA  
Questo prodotto è sostanzialmente  
Prodotto privo di classificazione di r  
n° 1272/2008. Informazioni applicat  
trattamenti e sulla base dei test ese  
Effetti potenziali sulla salute, segnali  
Occhi  
In alcuni individ  
Irritazione, arro  
Ingestione Se ingerito può  
Inalazione Elevate concent  
nausea.

#### SEZIONE III - COMPOSIZI

I componenti di questo prodotto NC  
ISOPROPYL ALCOHOL  
CAS 67-63-0 EINECS 200-661-7  
Xi, R 36 (Irritante per gli occhi)  
F, R 11 (Facilmente infiammabile)  
R 67 (Inalazione dei vapori può pro  
vocare sonnolenza e vertigini)



MSDS Material Safety Data Sheet - Version



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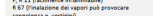
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MSDS Material Safety Data Sheet - Version 02 Data revisione 01.02.2021

# ALL COLORS are provided with SAFETY SHEET



# BIOLEK

MILANO

CHOOSE A RELIABLE AND SAFE BRAND  
FOR YOU AND YOUR CUSTOMERS.

