



Safety Data Sheet (SDS)

According to Commission Regulation (EU) 2020/2081 of 14 December 2020
amending Annex XVII to Regulation (EC) No 1907/2006 and REACH

VERSION 05 REVISION DATE 01.07.2022

BIOTEK srl Via R. Farneti 8 20129 Milano Italy P.I. 10911780152

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Trade name	BIOTEK
Product name	ROME
Product code	E15-09 18ml / E5-09 7ml
Description	Mixture for use in tattoos or permanent make-up
Manufacturer	BIOTEK srl Milano Via R. Farneti 8 Italy P.I. 10911780152
Contact	Phone +39.02.7380144 security@biotek.it
Product use	PMU exclusive professional use
Content	18ml 0.61 fl.oz / 7ml 0.24 fl.oz
Emergency	Contact the local poison center US 1 (800) 222-1222 American Association Poison Control Center

SECTION 2 - HAZARDS IDENTIFICATION

Emergency Class

This product is basically considered non-hazardous as per EC Regulation n.1272/2008
Product without risk classification to health and the environment according to CLP Regulation (CE)
n.1272/2008.

Information applicable to the quantities normally used in accordance with the practice of the treatment and on the basis of tests performed.

Potential Health Effects, Signs and Symptoms of Exposure:

Eyes	In some sensitive individuals, symptoms may include mildly to moderately irritation, redness, itching and watering.
Ingestion	If product is swallowed may cause nausea, vomiting and/or diarrhea.
Inhalation	High concentration of vapors can cause drowsiness, dizziness, headaches and/or nausea.
Skin	In sensitive people can cause irritation or allergic reaction.

SECTION 3 - COMPOSITION AND INGREDIENTS INFORMATION

Mixtures General Information

Concentrated dispersion of pigments in water solution of distilled water and glycerin.
The components of this product are not listed in Annex 3.1/ Regulation (CE) n.1272/2008 except
ETHANOL CAS 64-17-5 EINECS 200-578-6

Chemical Identity	CAS number	INCI name	EU class %	FDA %	Exposure OSHA	Limits ACGIH	Classification Annex 3.1 Reg. (CE) 1272/2008
<i>Liquid fraction (DILUENT)</i>							
Ethanol	64-17-5	Alcohol	10% - 25%	C	1000ppm*	1000ppm	H225 (Flammable)
Glycerin	56-81-5	Glycerin	10% - 25%	C	N/E	N/E	-
Distilled water	7732-18-5	Aqua	10% - 25%	C	N/E	N/E	-
Propylene Glycol	57-55-6	Propylene Glycol	1% - 5%	E	N/E	N/E	-
PVP	9003-39-8	PVP	P.F.	P.F.	N/E	N/E	-
Ricin Oil	9083-41-4	Ricin Oil	P.F.	P.F.	N/E	N/E	-
Aloe Barbadensis	85507-69-3	Aloe Barbadensis	P.F.	P.F.	N/E	N/E	-
Hamamelis Virginiana	84696-19-5	Hamamelis Virginiana	P.F.	P.F.	N/E	N/E	-
Polysorbate	9005-64-5	Polysorbate 20	P.F.	P.F.	N/E	N/E	-
Magnesium Aluminium Silicate	1327-43-1	Magnesium Aluminium Silicate	P.F.	P.F.	N/E	N/E	-
<i>Solid fraction (PIGMENT)</i>							
Iron oxide black	1317-61-9	77499	P.F.	P.F.	N/E	N/E	-
Iron oxide red	1309-37-1	77491	P.F.	P.F.	N/E	N/E	-
Iron oxide	51274-00-1	77492	P.F.	P.F.	N/E	N/E	-

N/E = NOT ESTABLISHED
N/R = NOT REVIEWED
N/DA = NO DATA AVAILABLE
N/A = NOT AVAILABLE
P.F. = PROPRIETARY FORMULA

* Listed substance potentially hazardous as defined by OSHA Hazard Communication Standard (29 CFR 1910.1200) OSHA in suspension in a gas if inhaled in excess of 1000ppm.

Class % indicates the range of concentrations as per CPNP portal according to EC Regulation 1223/2009

% FDA indicates the range as per the "Guide for Cosmetic Notification Form" - FDA / Health Canada

The% are expressed according to the weight / volume ratio

FDA-codes:

A1 = 75 – 100 % A2 = 50 – 75 % B = 25 – 50 % C = 10 – 25 % D = 5 – 10 % E = 1 – 5 % F = 0,1 – 1 % G = < 0,1

SECTION 4 - FIRST AID MEASURES

No injuries to the authorized personnel are known using the product. No self-protection is needed.

However, in case of need, you should take the following general measures and in the case of severe and not expected symptoms, consult a doctor.

First aid for Eye Flush with plenty of water for 15 minutes or use eyewash lotion. Seek medical attention.

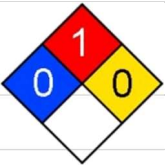
First aid for Skin First aid is not normally required, however, it is good practice for exposed area to be cleaned with soap and water.

First aid for Inhalation Remove individual from the contact with substance and move to fresh air.

First aid for Ingestion Do not induce to vomiting. Flush mouth with water. Contact anti-poison centre. Seek medical advice.

SECTION 5 - FIRE FIGHTING MEASURE

Special hazards arising from the substance or mixture: none known or to be expected.

FLASH POINT	FLAMMABLE LIMIT	AUTO IGNITION
> 105° C	NO DATA	425° C
The point of auto-ignition is dependent only on the component of alcohol		
Extinguishing Method	Use carbon dioxide (CO ₂) or dry chemical extinguisher or aqueous foam or water for large fires.	
Instructions	Use self-breathing device and personal protection equipment.	
Prohibited	None.	

SECTION 6 - ACCIDENTAL RELEASE MEASURE

No harm expected. Wear appropriate equipment/clothing during clean-up.

In case of fire, extinguish the sources of ignition or heat. Cover the spillage with absorbent material (eg vermiculite), collect most of the resulting mass and discard the remainder by spraying water.

If the product has escaped into a stream, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities. For waste disposal see additionally section 13.

SECTION 7 - HANDLING AND STORAGE

Do not eat, drink and/or smoke during handling. Clean already opened packages after usage. Follow the mandatory shelf life of the products before and after opening. Wash hands prior to use and follow local hygiene measures. Store sealed containers in a cool, dry place away from light and heat. Avoid direct exposure to the sun. The containers and empty containers can contain product residue and must be managed properly. Place the containers in such a way that the labels are clearly visible.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

No special precaution must be adopted for normal use.

Follow the techniques of good personal hygiene. Do not eat, drink or smoke while using the product.

Precautionary measures Allow adequate ventilation to the premises where the product is stored and / or handled.

Eye /face Protection Use chemical splash goggles

Skin Protection Use protective gloves made of natural latex, neoprene, PVC vinyl or Nitrile.

Respiratory Protection Not needed for normal use

The exposure limit for ethanol content, if inhaled by air is:

ACGIH-TLV 1000 ppm - OSHA-PEL 1000 ppm - TLV TWA 1000 ppm - 983 mg/m³

Eye/face protection Wear safety goggles where there is risk of eye contact.

Skin protection Wear suitable gloves.

Respiratory protection Provide adequate ventilation.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Creamy liquid
Odor	Neutral to slightly alcoholic
Color	Brown
Ph	4,5 - 7,5
Solubility in water	Diluent soluble in water at 20 ° C - Pigment insoluble.
Flammability	Non flammable

SECTION 10 - STABILITY AND REACTIVITY

The product is stable in normal conditions of use and storage. We are not aware of specific conditions that may result in hazardous reactions. The product is non-reactive and does not polymerize. At temperatures above 100 ° C it causes the evaporation of the liquid component of the product. Incompatible substances are not identified. Do not allow the product to come into contact with acids, bases, oxidizing and reducing agents that can cause a dangerous reaction.

SECTION 11 - TOXICOLOGICAL INFORMATION

The product does not have any known toxic or comparable adverse effects on human health. Information on likely routes of exposure

Ingestion	Ingestion may cause irritation and malaise.
Inhalation	Inhalation may irritate respiratory system.
Skin contact	No adverse effects known or expected.
Eye contact	Direct contact may irritate the eyes.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental stability	Use according to good working practices, avoiding disposal in the environment. Inform the relevant authorities if the product in large quantities, has reach waterways or sewers, and if it has contaminated soil or vegetation.
Effects on plants and animals	Not available.
Effects on aquatic life	Not available.

SECTION 13 - DISPOSAL CONSIDERATION

This product is not identified as a hazardous waste under RCRA 40 CFR 261, and is not regulated by CERCLA (Superfund). Dispose of residual waste should be in accordance with local regulations.

SECTION 14 - TRANSPORTATION INFORMATION

IMGD (maritime): not hazardous material
ADR (road transport): not hazardous material
RID (transport by rail): not hazardous material
IATA Regulation (transport by air): Not hazardous material
Transport / Additional information: The product is not dangerous

SECTION 15 - REGULATORY INFORMATION

EC Directive 2020/2081 REACH and amendments
EC Directive 1907/2006
EU Regulation ResAp(2008)1 on requirements and criteria for the safety of tattoos and pmu
Tätowiermittelverordnung 13.11.2008
EC Directive 1272/2008/EC Classification, labeling and packaging of substances and mixtures
EC Regulation 453/2010
EC Directive 2008/128/CE Colors for use in foodstuffs
EC Regulation No 1223/2009 on Cosmetic Products
OSHA Hazard Communication Standard - non-hazardous under 29 CFR 1910.1200

SECTION 16 - OTHER INFORMATION

Carefully follow the directions and recommendations of the MSDS.

Store in a cool place. Keep the original packing. Keep out of the reach of children.

The information and recommendations contained in this safety data sheet are based on data and sources believed to be accurate, and report the most reasonable and correct at time of preparation of the sheet. However, we do not grant any express or implied warranty as to the accuracy of the data or results obtained from the use of this product.

This data sheet gives the most important parameters and safety standards commonly accepted and cannot be considered an exhaustive document on the risks.

The information is provided in good faith and it is your responsibility to evaluate the correct conditions of use and applicable safety and environmental protection.

The company assumes no responsibility for personal injury and damage to persons and / or property damage caused by the product.

Instruction for use

Carefully follow the instructions on the label. The product is for professional use only. Avoid any use not expected by the manufacturer. Proper professional title of qualification is required for use.

To be used in combination with sterile /disposable accessories.

Do not reuse the product after having poured from the original container.

The professional must inform the customer about the message contained in the precautions and about the possible allergic reactions. Use prohibited for children under 18 years.

Label information

Product Name

Composition (INCI Nomination)

Batch number

Expiration Date (hourglass symbol)

Shelf life after opening product

REFERENCES

ResAP (2008) 1

HSDB

U.S. Department of Health and Human Services - NTP

NIOSH - Registry of Toxic Effects of Chemicals Substances

SAX - Dangerous Properties of Industrial Materials

DEFINITIONS OF TERMS AND LABELS

On the MSDS sheet appears many abbreviations, acronyms and labels. Some of the most used are listed below:

CAS No.	Chemical Abstract Service Number
EXPOSURE THRESHOLD IN AIR	
ACGIH	American Conference Gov.Ind.Hygienists
TLV	Threshold Limit Value
OSHA	Occupation Safety Health Administration
PEL	Permissible Exposure Limit
IDLH	Immediately Dangerous Life and Health
OTHER STANDARD ABBREVIATIONS	
NA	Not Available
NR	No Results
NE	Not Established
ND	Not Determinated
ML	Maximum Limit

Health Hazard

4 Deadly
3 Extreme Danger
2 Hazardous
1 Slightly Hazardous
0 Normal Material

Flash Points Fire Hazard

4 Below 73°F
3 Below 100°F
2 Between 100°F and 200°F
1 Above 200°F
0 Will Not Burn

Specific Hazard

ACID - Acid
ALK - Alkali
COR - Corrosive
OXY - Oxidizer
☢ - Radioactive
☞ - Use No Water

Reactivity

4 May Detonate
3 Shock/Heat May Detonate
2 Violent Chemical Change
1 Unstable If Heated
0 Stable

TOXICOLOGICAL INFORMATION	
LD 50	Lethal dose (liquid) which kills 50% of exposed animals
LC 50	Lethal concentration (gas) which kills 50% of exposed animals
ppm	Concentration expressed in parts per million
Tdlo	Lowest dose to cause a symptom
Tclo	Lowest concentration to cause a symptom

PERSONAL PROTECTION INDEX			
A		G	
B		H	
C		I	
D		J	
E		K	
F		X	Consult your supervisor or S.O.P. for 'SPECIAL' handling directions
A		n	
o		p	
q		r	
s		z	
t		u	
w		y	

Pericoli di Tipo Fisico Chimico				
Esplosivo	Gas sotto pressione	Infiammabile	Ossidante	Corrosivo
Pericoli per la Salute			Pericoli per l'Ambiente	
Tossico acuto	Gravi effetti per la salute	Effetti più lievi per la salute	Pericoloso per l'ambiente	