DEPILIA®

QUALITATIVE AND QUANTITATIVE COMPOSITION

BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
DEPILIA	PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	8024116002750

INGREDIENTS (INCI)	CAS NR.	EINECS NR.	%	FUNCTION	INGREDIENTS (CTFA)
Colophonium	8050-09-7	232-475-7	41,00000	Binding, Depilatory, Film forming, Viscosity controlling	Colophonium
Glyceryl rosinate	65997-13-9; 8050-31-5	266-042-9; 232-482-5	23,00000	Film forming, Perfuming	Glyceryl rosinate
Hydrogenated microcrystalline wax	64742-60-5; 92045-76-6	265-163-4 (I); 295-458-3 (I)	20,00000	Binding, Emulsion stabilising, Viscosity controlling	Hydrogenated microcrystalline wax
Paraffin	8002-74-2; 64742-51-4	232-315-6; 265-154-5	15,55000	Emollient, Viscosity controlling	Paraffin
Azulene	275-51-4	205-993-6	0,25000	Skin conditioning, Soothing	Azulene
C.I. 60725	81-48-1	201-353-5	0,10000	Cosmetic colorant	Violet 2
C.I. 61565	128-80-3	204-909-5	0,10000	Cosmetic colorant	Green 6
			100,0000		

European Association of Poison Centers and Clinical Toxilogists (EAPCCT) & European Cosmetic Toiletry and Perfumery Association (COLIPA), European Commission database with information on cosmetic substances and Ingredient (COSING).

For **Dana Italia s.r.l.**

Dott. **Alberto Allegretti**

Position
Cosmetic Product Safety Evaluator (according to European Rules 1223/2009)

DANAGROUP®

Dana Italia s.r.l.
Sede Legale: Via Roma, 157 - 80029 Sant'Antimo (NA) Italia
Stabilimento: Zona Industriale A.S.I. - 81032 Carinaro (CE) Italia
Tel.: +39 081 5016019 - Fax: +39 081 8911459 - info@danagroup.it

Intesa Sanpaolo S.p.A.: Agenzia di Teverola (CE)- IBAN: IT 61 X 03069 75084 100000004532 - SWIFT: BCITITMM
Cariparma S.p.A.: Agenzia di Giugliano in Campania (NA) - IBAN: IT 13 F 06230 39900 000056894484 - SWIFT: CRPPIT2P519
Pec: danaitaliasrl@legalmail.it - P.IVA/C.F.: IT 02604291217 - C.C.I.A.A. 501897
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DEPILIA®

DECLARATION

BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
DEPILIA	PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	8024116002750

CONFORMITY CERTIFICATE

Released by **Dana Italia S.r.l.** Via Roma, 157 - 80029 Sant'Antimo (NA) Italy

Manufacturer of depilatory waxes intended for professional use on the basis of checks carried out during the of production and business management.

DECLARES

That our products are in accordance with current regulations of the 1223/2009 and in accordance with the New European Cosmetic Regulations.

For more information, please refer to the technical documentation for **Dana Italia S.r.l.**

For **Dana Italia s.r.l.**

Dott. **Alberto Allegretti**

Position
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DEPILIA®

PHYSICO-CHEMICAL SPECIFICATIONS OF THE FINISHED PRODUCT

BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
DEPILIA	PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	8024116002750

SPECIFICATION	RESULT RANGE	METHOD
PHYSICAL AND CHEMICAL PROPERTIES GENERAL INFORMATION		
Chemical identification	Mixture composed by natural and synthetic ingredients	
Aspect	Highly thick fluid	Visual examination
Color	Dark blue	Visual examination
Smell	Neutral	Olfactory
PHYSICAL PROPERTIES		
Viscosity	8.000-11.000	Brookfield RVDV-I Prime, cPs, (spindle 03 - RPM 5 a 65.0°C)

CHEMICAL PROPERTIES	
pH	Not-determined (not water-based product)
Boiling point	>120°C
Density (20°C)	0,8---0,98 g/cm3
Flammability limits	Not-flammable
Solubility in water	Insoluble
Solubility in hydrocarbons solvens	Very soluble
Total viable count	Not determined because product is totally waterless and microbial growthis not possible
Pathogenic microorganisms	Absence

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CERTIFICATE OF ANALYSIS

BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
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PARAMETER	RESULTS	MEASURE UNIT	METHOD	ACCPTED RANGE
VISCOSITY	10.874	CPS	BROOKFIELD RVDV-I PRIME 65°C	8.000 - 11.000
COLOR	OK	COMPARISING WITH INTERNAL STANDARD	COMPARISING WITH INTERNAL STANDARD	XXXXXXXX
SMELL	TYPICAL	COMPARISING WITH INTERNAL STANDARD	COMPARISING WITH INTERNAL STANDARD	XXXXXXXX
SOFTENING POINT	54.1	°C	METTLER TOLEDO DP 70 ASTM D6090	55° ± 1°C

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DEPILIA®

SPECIFICATIONS OF PACKAGING MATERIALS

BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
DEPILIA	PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	8024116002750

MATERIAL USED	SPECIFICATION OF MATERIAL USED
POT	Metallic POT
Case POT	Carton print
Carton	Folding 24 pieces

This package protects formulation against oxygen and light, and allow a good application of wax on the skin.

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PRODUCT NAME

PENTOLINO
CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml

All cosmetic products manufactured by **Dana Italia s.r.l.** comply with the Good Manufacturing Practice (GMP) conformity with EU regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products. As an example of manufacturing process, we report a part of Batch card, with instruction for operators.

OPERATIVE PROCESS

Clean the kettle and all other mixer or flask that will be used for production, according to clearing procedure. Weight off raw materials. Proceed with methodic as described in approved batch card.

Manufacturer of depilatory waxes intended for professional use on the basis of checks carried out during the of production and business management.

PHASE A

INGREDIENTS	%	QUANTITY KG	LOT #	CHECK
COLOPHONIUM				☐
GLYCERYL ROSINATE				☐
HYDROGENATED MICROCRYSTALLINE WAX				☐
PARAFFIN				☐
AZULENE				☐
C.I. 60725				☐
C.I. 61565				☐

PHASE A

Weigh out all ingredients of phase A and put them into the kettle. Heat until temperature has reached 110° - 115 °C. Start to mix. If the product is competely clear, and you'll start filling the cassettes, make sure the product is between 85° - 90°C.

For **Dana Italia s.r.l.**

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BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
DEPILIA	PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	8024116002750

For a good testing procedure, is important that the mix reach a good equilibrium of chemical, physical and viscosity features; for this reason , wait 3 hours before testing product, during this period , hold product at a temperature around 85°C under stirring. After this period, start with test on bulk, following the QC protocol, approved from company. If the batch pass all tests, proceed with packaging.

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DEPILIA®

MICROBIOLOGICAL SPECIFICATIONS OF THE FINISHED PRODUCT

BRAND NAME	PRODUCT NAME	PRODUCT BARCODE
DEPILIA	PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	8024116002750

SPECIFICATION	
Bacterial count	Not-determined (not water-based product)
Fungus count	Not-determined (not water-based product)
Escherichia coli	Not-determined (not water-based product)
Salmonella	Not-determined (not water-based product)
Stapphylococcus aurens	Not-determined (not water-based product)
Pseudomonas aeruginosa	Not-determined (not water-based product)

INFORMATION ON RESISTENCE TO MICROBIAL CONTAMINATION	
Microbial attack (Challenge Test)	Not-determined (not water-based product)
Preservative system	The product does not need preservatives

Conclusion: product CONFIRMS on the level of its microbiological quality.

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PRODUCT NAME

PENTOLINO
CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml

The objective of this stability report is to ensure that product maintains is intended physical, chemical and microbiological quality, as well as functionally and aesthetics when stored under appropriate conditions. The features and the results of study protocol are specified in document relative to "Physical, Chemical and Microbiological Specifics".

STABILITY

This product doesn't contain water, so is highly not probable the microbiological contamination; other substances used as ingredients have all a very high chemical stability and are resistant to oxidation by oxygen contained in atmospheric air; hygroscopic ingredients are not present, for this reason is not possible the presence of water coming from atmosphere. This product can be defined stable and without modification, for three years if stored under appropriate condition and in the original packaging, without opening. This product can be defined stable and without modification, for three years if stored under appropriate condition and in the original packaging, without opening.

STABILITY TEST

This product passed all stability tests, performed in the factory, according to internal test protocol . during tests, the products is put under conditions that can accelerate all phenomena of not stability. At the end of stability tests the product is evacuate for the potential interactions between product and the packaging that might occur during Thermo-Shock Test. This product can be defined stable and without modification , for three years if stored under appropriate condition and in the original packaging, without opening.

HEAT-SHOCK TEST

The aim of this test is to accelerate, the most is possible, the phenomena of "aging" of cosmetic product, for discovering any not stability in a short time.
Product, in his final packaging, has been stored at room temperature for 24 hours, after, it has been stored at -10°C for 24 hours, after, put in professional heater for cartridges of depilatory waxes for 24 hours; at the end, stored at room temperature after this Heat-Shock Cycle, all eventual modifications have been evaluate and compared with a sample, stored always at room temperature and considered as the referring sample. The Heat-shock Test is repeated on the same sample for three cycles.

COMPATIBILITY CONTENT/ BOX

After Heat Shock Cycle have been evaluated all phenomena on packaging such as:

- increased weakness
- brocken areas
- deformations
- change of color and transparence
- change of permeability
- loss of product
- problems with product exit
- label deformation or lowering of coloration
- blockage of opening system
- color transfer from product to packaging

Conclusion: this product, under all stability simulations, doesn't showed any change that induced to change formulation or packaging or labeling or production cycle. It is stable when stored and handled under appropriate conditions. PAO IS 24 MONTHS.

For **Dana Italia s.r.l.**

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TEST	RELEASE CRITERIA	RESULTS	TECHNIQUE
Appearance	Higly dense liquid	Complies	Visual inspection
Color	Characteristic	Complies	Visual inspection
Odour	Characteristic	Complies	Olfactory
pH	Not-determined (not water-based product)	Complies	pH meter
Water bath	Water bath complies with standard	Complies	Water bath machine
Viscometer	Viscometer complies with standard	Complies	Viscometer machine

IDENTIFICATION, MANUFACTURING DATE, EXPIRED DATE

BATCH NO.	MANUFACTURING DATE	EXPIRED DATE
049191	04-02-2019	04-02-2022

STORAGE CONDITIONS AND PACKING
Room Temperature: 10°C > 35°C
Packaging: METALLIC POT

FREQUENCY TEST
Each production is analyzed and subjected to accelerated aging tests (**Incubator and Thermal Shock**).

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DEPILIA®

REAL TIME STABILITY DATA

RESULT OF TEST DURING STORAGE AT 40°C (± 2°C) AND THERMIC SHOCK ON THE PRODUCT

PRODUCT NAME	SHELF LIFE	
PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	36 MONTHS	Result of test during, storage at 40°C (± 2°C) and thermic shock on the product.

TIME	APPEARANCE	COLOR	ODOUR	pH	WATER BATH	VISCOSITY	MICROBIAL LIMIT
Limit	Wax	Characteristic	Characteristic	Not-determined	Complies	Complies to standard	Complies to manufacture specification
Initial	Complies	Complies	Complies	Complies	Complies	Complies	Complies
3 Months	Complies	Complies	Complies	Complies	Complies	Complies	Complies
6 Months	Complies	Complies	Complies	Complies	Complies	Complies	Complies

Conclusion: stability data still under study, according to our observations, we certify the shelf life of PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml WILL BE STABLE FOR 36 MONTHS.

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PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml	36 MONTHS	Result of test during, storage at 40°C (± 2°C) and thermic shock on the product.

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Limit	Wax	Characteristic	Characteristic	Not-determined	Complies	Complies to standard	Complies to manufacture specification
Initial	Complies	Complies	Complies	Complies	Complies	Complies	Complies
3 Months	Complies	Complies	Complies	Complies	Complies	Complies	Complies
6 Months	Complies	Complies	Complies	Complies	Complies	Complies	Complies

Conclusion: stability data still under study, according to our observations, we certify the shelf life of PENTOLINO CERA A CALDO LIPOSOLUBILE 3.3 AZULENE 100 ml WILL BE STABLE FOR 36 MONTHS.

For **Dana Italia s.r.l.**

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