COSMETICS LAB

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# SAFETY ASSESSMENT

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|---|---|
| **CUSTOMER** | PROCYTE, A PHOTOMEDEX COMPANY |
| **PRODUCT** | NEOVA MICRODERMABRASION CREAM |
| **FORMULA REF** | 012811-21 |

## LEGISLATION

This document addresses the requirements of the EU for an assessment of safety for human health of finished cosmetic products (Statutory Instruments 2008 No. 1284, The Cosmetics Products (Safety) Regulations 2008) and subsequent amendments by considering the general toxicological profile of the ingredients and an assessment of the final product as sold.

## 1. COMPANY POLICY

This product and its ingredients have been assessed to ensure compliance with company policy requirements for product safety assessment.

## 2. PRODUCT COMPOSITION

Aqua
Alumina
Ethylhexyl Palmitate
Sodium Coco-Sulfate
Stearic Acid
Cetyl Alcohol
Glyceryl Stearate
PEG-100 Stearate
Polyacrylamide
Magnesium Aluminium Siliate
Butylene Glycol
Triethanolamine
Sodium Chloride
Sodium Sulfate
Coconut Alcohol
PEG-150 Distearate
Phenoxyethanol
Caprylyl Glycol
Ethylhexylglycerin



Registered in England 6708989 The Granary Hermitage Court Hermitage Lane Maidstone ME16 9NT

Caprylic/Capric Triglyceride
Hexylene Glycol
Sodium Benzoate
Potassium Sorbate
Mentha Piperita (Peppermint) Oil
C13-14 Isoparaffin
Laureth-7

**3. INCIDENTAL MATERIALS**

Other materials present in the product have been introduced as secondary or minor parts of the principal ingredients; these additives have been checked and all are deemed safe for use in the finished product at the concentrations advised. Where the materials are preservatives their total concentrations do not exceed the provision of current EU legislation.

**4. CLAIMS**

The issuing of a safety assessment is not an endorsement of the validity, accuracy or appropriateness of any of the products claims or benefits.

**5. TRIETHANOLAMINE AND ITS SALTS**

These materials have the potential to form nitrosamines and are regulated under Annex III part I Item No 62. The maximum secondary amine content should not exceed 0.5% in the material. The purity must be 99% minimum. They must not be used with nitrosating systems. The maximum nitrosamine content must not exceed 50µg/Kg. Keep in nitrite free containers.

**6. ACRYLAMIDE**

The level of Acrylamide monomer must not exceed 1ppm.

**7. PRESERVATION**

This assessment is only valid if the product is adequately preserved. If it is not, there is the potential for microbial growth which could cause a hazard to health so preservative efficiency must be evaluated by conducting a challenge test.

**8. ASSESSMENT OF SAFETY OF THE FINISHED PRODUCT**

The product is based on conventional cosmetic ingredients for this type of product. Similar formulations have been marketed for many years without significant adverse effects. **If the issues mentioned are observed and adhered to,** then the product is not considered to represent any undue hazards with respect to human health in normal use and under reasonably foreseeable misuse.

This assessment is based on information supplied by the client, material manufacturers and from published information in recognised authoritative sources and, whilst best endeavours have been used to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied to it and used for preparing this assessment.

In order for this assessment to remain valid, any perfume, essential oil or flavour added to this product must comply with the most recent IFRA guidelines at its level of use in this product type.

The specification of any colorant added to these products must comply with the requirements of the EU Cosmetics Directive Annex IV Part 1.

This assessment is based on the legislation and Industry guidelines as pertaining at the time of signature. It is the responsibility of the recipient to ensure that all future legislation, guidelines, such as those issued by IFRA, and any other relevant safety issues are adhered to.

This assessment has been made assuming the manufacture of the products named is carried out in accordance with the principle of good manufacturing practice.

The packaging must be safe to use and the wording on this plus that in any literature or advertising should include adequate and suitable instructions and warnings where appropriate and must not compromise the products safety through inadequate or incorrect information.

Where a raw material has an EU specified quality then the material must comply with the relevant specification for this assessment to remain valid.

**9. NEW COSMETIC REGULATIONS 2013**

This assessment is only valid under the existing EU Cosmetics Directive. From July 11th 2013 all cosmetic products that have been on the market prior to that date should have been registered on a central EU website under the new cosmetic regulations in order to continue to be legally sold in the EU. On this date the Cosmetics Directive will be repealed.

The registration process, to be known as 'Notification', will commence on January 11th 2012.

These new regulations will require a new, far more detailed, assessment and so this assessment will not be valid after July 11th 2013 or after a product has been 'notified' if sooner. The new regulations will also require the 'Responsible Person' to provide a lot of extra information. Some of this information will be used by the Safety Assessor to compile the new safety assessment.

Signed: D R Munden B.Sc., C.Chem., M.R.S.C. _____ Date: 19 May 2011
On behalf of Cosmetics Laboratory Ltd