

SAFETY ASSESSMENT

CUSTOMER	PROCYTE, A PHOTOMEDEX COMPANY
PRODUCT	NEOVA HERBAL WASH
FORMULA REF	11493

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
Aloe Barbadensis Leaf Juice
Disodium Lauroamphodiacetate
Methyl Gluceth-20
Carbomer
Ethylhexylglycerin
Hexylene Glycol
Panthenol
Phenoxyethanol
Potassium Hydroxide
Sodium Trideceth Sulfate
Xanthan Gum
Tilia Cordata Flower Extract
Chamomilla Recutita (Matricaria) Flower Extract
Allantoin
Butylene Glycol
Calendula Officinalis Flower Extract
Anthemis Nobilis Flower Extract
Centaurea Cyanus Flower Extract
Hypericum Perforatum Flower/Leaf/Stem Extract
Methylisothiazolinone

Mentha Piperita (Peppermint) Oil
Tetrasodium Glutamate Diacetate

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. 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.

6. ESSENTIAL OILS

The assessment of this product has been based on the formulations provided. Any deviation from the concentrations of the essential oils indicated may increase the level of photosensitisers, other restricted materials or allergens and make the formulations unsafe for use.

7. ALLERGENS

Added perfumes, flavours or essential oils may contain one or more of the EU Cosmetics Directive Annex III part 1 listed allergens. Any of these allergens individually exceeding 0.001% in the product must be listed in the Ingredient listing.

8. LIMONENE AND LINALOOL

Natural products containing substantial amounts of Limonene and/or Linalool should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxides per litre, determined according to the FMA method.

9. 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.

Signed: D R Munden B.Sc., C.Chem., M.R.S.C. 
On behalf of Cosmetics Laboratory Ltd

Date: 04 June 2010