ANIOSAFE MANUCLEAR NPC HF

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laboratoires ANIOS
Le professionnel de la désinfection

Summary

ANIOSAFE MANUCLEAR NPC HF

Informations réglementaires et générales

Regulation and general information

ANIOSAFE MANUCLEAR NPC HF est conçu, produit et contrôlé par les Laboratoires ANIOS, certifiés par l'AFAQ sous le numéro 1995/3723, selon le référentiel d'Assurance Qualité ISO 9001.

ANIOSAFE MANUCLEAR NPC HF *is designed, produced and controlled by the Laboratoires ANIOS, certified by the AFAQ Organism under the number 1995/3723 in accordance with the ISO 9001 Quality System*

La formulation de l'**ANIOSAFE MANUCLEAR NPC HF** répond aux exigences du règlement (CE) N°1223/2009 relatif aux produits cosmétiques.

ANIOSAFE MANUCLEAR NPC HF *formulation fulfils the requirements of the regulation (EC) No 1223/2009 relating to Cosmetic products*

ANIOSAFE MANUCLEAR NPC HF est étiqueté conformément à la réglementation Européenne relative à la classification et l'étiquetage des produits chimiques.

ANIOSAFE MANUCLEAR NPC HF *is labelled in accordance with the European regulation related to the classification and labelling of chemical products*

ANIOSAFE MANUCLEAR NPC HF répond à notre engagement volontaire d'Eco-conception repris dans notre charte ANIOSAFE.

ANIOSAFE MANUCLEAR NPC HF *meets our voluntary eco-design commitment included in our ANIOSAFE charter*

1921_FIRG_FR-EN_01-07-2013

ANIOSAFE MANUCLEAR NPC HF

Composition

Agents lavants / Washing agents

Cocamidopropyl betaine / Cocamidopropyl betaine

Sodium C14-17 alkyl sulfonate / Sodium C14-17 alkyl sulfonate

Agents conservateurs / Preservative agents

Alcool benzylique / Benzyl alcohol

Benzoate de sodium / Sodium benzoate

Agent hydratant / Moisturizing agent

Glycérine / Glycerin

Autres ingrédients / Other ingredients

Agent viscosant / Viscosing agent

Excipients / Excipients

1921_Composition_FR-EN_30-03-09.doc

ANIOSAFE MANUCLEAR HF
ANIOSAFE MANUCLEAR NPC HF

Stabilité et conditions de conservation
Stability and storage conditions

Produit pur non dilué

-Stockage entre +5°C et +35°C.

- Stabilité :

- Flacon non ouvert et poches airless : 30 mois à partir de la date de production indiquée sur l'étiquette.
- Flacon ouvert en cours d'utilisation : 3 mois selon une étude d'aérobiocontamination.

Pure product not diluted :

- Storage between +5°C and +35°C

- Stability :

- Not opened bottle and airless bottles: 30 months from the manufacturing date indicated on the label.
- Opened bottle being used: 3 months according to an aerobiocontamination study.

Révisé le 30/03/2009
Revised on 30/031/2009

ANIOSAFE MANUCLEAR NPC HF

Propriétés antimicrobiennes

Antimicrobial properties

Evaluation de la protection antimicrobienne d'un produit cosmétique, selon la norme NF EN ISO 11930 (Juin 2012).

Assessment of the antimicrobial protection of a cosmetic product according to the NF EN ISO 11930 standard (June 2012)

L'essai consiste en un essai d'efficacité de la protection antimicrobienne d'une formulation. L'essai réalisé permet d'apprécier la protection antimicrobienne (test d'épreuve) en suivant l'évolution de populations microbiennes introduites dans des échantillons d'un même lot maintenu à température ambiante.

The test is an efficacy test to control the antimicrobial protection of a cosmetic formulation The test realised permits to estimate the antimicrobial protection (Challenge test) by analysing the microbial population introduced in samples from a same batch number, maintained at room temperature.

ANIOSAFE MANUCLEAR NPC HF satisfait aux exigences de la Norme Internationale NF EN ISO 11930 avec un risque microbiologique considéré comme acceptable : la capacité de conservation antimicrobienne est conforme au critère A.

ANIOSAFE MANUCLEAR NPC HF satisfies the requirements of the NF EN ISO 11930 International Standard with a microbiological risk considered as acceptable: capacity of antimicrobial preservation is in compliance with the criteria A.

1921_protection_FR EN_30018_15-07-2013

ANIOSAFE MANUCLEAR NPC HF

Propriétés antimicrobiennes

Antimicrobial properties

Evaluation de la capacité de résistance à la contamination microbienne d'un produit cosmétique, selon une adaptation de la méthodologie décrite dans la Pharmacopée Européenne 6ème édition "Efficacité de la conservation antimicrobienne".

Assessment of the resistance power of a cosmetic product to the microbial contamination according to an adaptation of the method described in the European Pharmacopoeia 6th edtion "Efficacy of the antimicrobial preservation"

L'essai réalisé permet d'apprécier la capacité de résistance à la contamination microbienne d'un produit en suivant l'évolution de populations microbiennes introduites dans des échantillons d'un même lot maintenu à température ambiante.

The test realised permits to estimate the resistance power of a product to the microbial contamination by analysing the microbial population introduced in samples from a same batch number, maintained at room temperature.

La capacité de conservation antimicrobienne de l'ANIOSAFE MANUCLEAR NPC HF est conforme aux critères de la Pharmacopée Européenne 6ème édition après 28 jours.

La capacité de résistance à la biocontamination répétée de l'ANIOSAFE MANUCLEAR NPC HF est validée après 15 semaines d'essais, selon les conditions expérimentales décrites dans le rapport d'expertise.

The antimicrobial prewservation of ANIOSAFE MANUCLEAR NPC HF is in compliance with the criteria of the European Pharmacopoeia 6th edition, after 28 days.

The resistance to the repeated bio-contamination of ANIOSAFE MANUCLEAR NPC HF is assessed after 15 weeks testing, according to the experimental conditions described in the expertise report.

1919_résistance_FR EN_24421_30-03-2009

ANIOSAFE MANUCLEAR NPC HF

Propriétés antimicrobiennes

Antimicrobial properties

Evaluation de la capacité de résistance à la contamination microbienne d'un produit cosmétique, pendant son utilisation

Assessment of the resistance power of a cosmetic product to the microbial contamination during its use

L'essai réalisé permet d'apprécier la capacité de résistance à la contamination microbienne d'un produit en analysant la flore mésophile totale présente dans le flacon en cours d'utilisation.

The test realised permits to estimate the resistance power of a product to the microbial contamination by analysing the total mesophile flora present in the bottle during use.

Aucune croissance microbienne n'a été décelée après 12 mois d'utilisation. Tout flacon ouvert de ANIOSAFE MANUCLEAR NPC HF peut être utilisé pendant 12 mois.

No microbial growth was found after a 12 months use. Then any opened bottle of ANIOSAFE MANUCLEAR NPC HF can be used for 12 months.

1921_aérobiocontamination_FR EN_37917 & 37918_22-03-2019

EVIC france

PATCH TEST UNDER DERMATOLOGICAL CONTROL

SUMMARY OF THE STUDY REPORT

1. AIM AND PRINCIPLE OF THE STUDY

Checking of the skin compatibility of a liquid soap: **ANIOSAFE MANUCLEAR HF - Reference 1919000 – Batch: M01202, diluted at 5% in water for injection**, after single application to the skin (upper back) under exaggerated experimental conditions (under semi-occlusive adhesive, for 48 hours).

Checking of the skin compatibility of the test product: 15 minutes after patch removal, visual skin examination and questioning of the subjects, by the Dermatologist or the technician in charge.

2. DATES OF THE STUDY PERFORMANCE: from March 28th to 30th, 2011

3. VOLUNTEERS

- Number of volunteers defined in the protocol : **10**
- Number of volunteers whose data are exploitable: **11** (**10** included, 1 exclusion (ref. 7) for inexploitable results)
- Description of the main characteristics of the panel (valid cases):
  - Age: mean 40, between 19 and 68
  - Sex: 6 female and 4 male
  - Phototype: I to IV
  - Skin type: all skin types on body (back)

4. RESULTS – DISCUSSION

Investigational Product Denomination, reference, batch, dilution	**Type of patch**	**Control time after patch removal**	**Type of reaction**	**Number of reactive subjects**	**% of reactive subjects**	**Mean daily irritation score Mdis**	**Skin compatibility of the product**
ANIOSAFE MANUCLEAR HF - Reference 1919000 – Batch: M01202, diluted at 5% in water for injection	Semi-occlusive TruMed®	T15 minutes (D3)	None	0	0 %	0	Very good skin compatibility

5. SIGNATURES AND DATES

Investigator: Dr Françoise MAGNE (Dermatologist)

Quality Assurance Personnel: Danièle PICARD

28.04.11

J. MAGNE p/o

SPONSOR: **LABORATOIRES ANIOS**
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CONFIRMATION IN HUMAN OF THE SKIN COMPATIBILITY AND ABSENCE OF ALLERGENIC POTENTIAL OF ONE COSMETIC PRODUCT AFTER REPEATED APPLICATION UNDER PATCH

Human repeated insult patch test

SUMMARY OF THE STUDY REPORT

AIM AND PRINCIPLE OF THE STUDY

This study intended to confirm the skin compatibility and the absence of allergenic potential of the cosmetic product **ANIOSAFE MANUCLEAR HF - Réf. 1919000 - Lot: M01202 diluted at 5% with distilled water,** after repeated application to the skin under exaggerated experimental conditions.

The product was applied under patch for a defined time. The applications were repeated 9 times over a period of 3 consecutive weeks, period necessary for the possible induction of an allergy.

After a minimal 2-week rest period, with no treatment, a single application of the product under patch, to the induction site and to a virgin site and for a defined time, enabled to reveal a possible induced allergy.

DATES OF PERFORMANCE OF THE STUDY: from May 02nd to June 11th, 2011.

VOLUNTEERS

- **Number of volunteers defined in the protocol: 100**
- **Number of volunteers whose data are exploitable: 107** (108 volunteers included, 1 volunteer discontinued (ref. 107) for personal reasons independent of the study and no exclusion was decided by the investigator).
- **Specific inclusion criteria:**

- age: 18 to 70 years old,
- sex: male and/or female,
- phototype (Fitzpatrick): I to V,
- 50% of the panel with all types of skin on body,
- 50% of the panel with reactive skin on body.

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SUMMARY OF THE METHODOLOGY

The experimental conditions defined in the protocol were the following ones:

Patch material	Experimental conditions of use	Quantity applied
TruMed®	Diluted at 5% with distilled water	160 µl

The applications of the test product, the removal of the patches and the controls were performed by the dermatologist or the technician in charge of the study.

- **Induction phase:** 3 consecutive weeks.

  * application of the product to a perfectly delimited site, under patch on D1, D3, D5, D8, D10, D12, D15, D17, D19.

  * patch removal
    - after 48 h of contact on D3, D5, D10, D12, D17, D19.
    - after 72 h of contact on D8, D15, D22.

  * controls: skin examination and questioning before patching on D1 and about 15 minutes (or more, if redness appeared after removal of the adhesive), after patch removal on D3, D5, D8, D10, D12, D15, D17, D19, D22.

- **Rest period:** 2 consecutive weeks at least (4 weeks at the most).

  * no application of product.

- **Challenge:** 1 week.

  * application of the product to a perfectly delimited virgin site and to the site defined for the induction phase, under patch on D37.

  * patch removal after 48 h of contact on D39.

  * controls: skin examination and questioning before patching on D37 and about 15 minutes (or more, if redness appeared after removal of the adhesive), after patch removal on D39, D40, D41 (48, 72, 96 h after application).

RESULTS

Induction phase	
Type of reactivity on the induction site	**Number and percentage of reactive volunteers**
None	0 / 0 %

Challenge	
Type of reactivity on the induction site and virgin site	**Number and percentage of reactive volunteers**
None	0 / 0 %

CONCLUSION

Under the experimental conditions adopted the repeated applications of the product **ANIOSAFE MANUCLEAR HF - Réf. 1919000 - Lot: M01202 diluted at 5% with distilled water,** under semi-occlusive patch, induced no reaction of irritation and the product **has a very good skin compatibility.**

Moreover, the repeated applications **induced no allergic reaction.**

Signatures and dates

Investigator: Doctor Rozalia OLSAVSZKY (dermatologist) 29/06/2011

Quality Assurance Personnel: Lucia CHIRITA 29/06/2011

Head manager of the investigator centre: Alina NANU 29/06/2011

EVIC france

IN USE TEST UNDER DERMATOLOGICAL AND OPHTHALMOLOGICAL CONTROLS

SUMMARY OF THE STUDY REPORT

1. AIMS AND PRINCIPLE OF THE STUDY

Checking of the skin and eye acceptability and subjective assessment of the cosmetic qualities and efficacy of the product **ANIOSAFE MANUCLEAR HF Reference 1919000 – Batch: M01202**, after use at home at least once a day for general **face and body** hygiene (shower if possible) and 5 times a day or more for the hands washing, under the normal conditions of use planned by the Sponsor, for 21 consecutive days.

Checking of the skin and eye acceptability:

- Visual skin examination of the experimental areas (face and body) by the dermatologist, before then after 21 consecutive days of product use
- Ophthalmological examination by the ophthalmologist, before and after the first application, then after 21 consecutive days of product use
- Analysis of the sensations of discomfort reported by the volunteers directly to the investigator and/or co-investigator or technician during the study or in their daily log

Subjective assessment of the cosmetic qualities and efficacy of the product at the end of the study, using a target questionnaire.

2. DATES OF THE STUDY PERFORMANCE: from April 14th to May 17th, 2011

3. VOLUNTEERS

- Number of volunteers defined in the protocol : **25**
- Number of volunteers whose data are exploitable: **26** (**27** included, 1 exclusion (ref. 25) for non respect of the protocol was decided by the investigator)

- Description of the main characteristics of the panel (valid cases):
  - Age: mean 40, between 19 and 69
  - Sex: 24 women and 2 men
  - Phototype: I to IV
  - Skin type: all skin types on face and body
  - Reactive (sensitive) skin on face and body
  - Regular use of liquid soap.

4. RESULTS – DISCUSSION

4.1. Skin acceptability

No clinical sign imputable to the investigational product was noted by the dermatologist.

Reference of the concerned volunteers	Sensations of discomfort felt (imputable to the investigational product)	% of concerned volunteers
Ref. 22 (combination skin on face and normal skin on body)	Very slight dryness and pulling of the hands after each application during the drying from D1 to D end, for 15 minutes.	**4%**

Discussion: the sensations of discomfort being relatively slight and of short duration, and occurring only on hands for one volunteer only, the investigator judged them acceptable for this type of product.

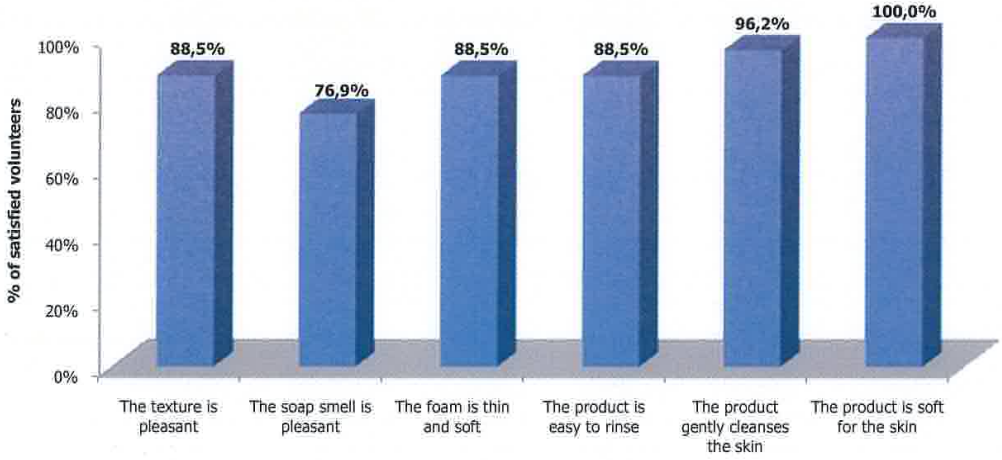
4.2. Eye acceptability

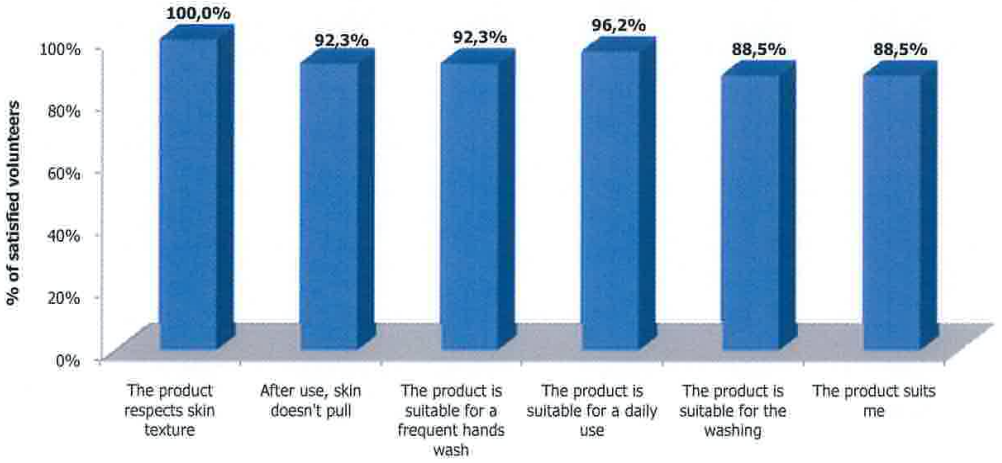
No clinical sign imputable to the investigational product was noted by the ophthalmologist.
No sensation of discomfort was reported by the volunteers.

CONCLUSION - Skin and eye acceptability of the investigational product

○ Good skin acceptability ☒	○ Very good eye acceptability ☒

4.3. Assessment of the cosmetic qualities and efficacy (self-assessment)





	The smell onto the skin after washing is not perceptible			(*) If Disagree, in case of perceptible smell after washing, is this one pleasant?	
Answer	**Number**	**%**	**Answer (on 4 volunteers)**	**Number**	**%**
	of volunteers who answered			**of volunteers who answered**	
Agree	22	**84.6%**	Agree	2	**50.0%**
Disagree (*)	4	**15.4%**	Disagree **	2	**50.0%**

(*) Why: the smell remains onto the skin, 1 ; slight and pleasant fragrance perceptible smell, 1 ; unpleasant smell, 1.

(**) Why: not pleasant, 1 ; persisting smell, 1.

5. SIGNATURES AND DATES

Investigator: **Dr Françoise MAGNE (dermatologist)**

14.06.11

Co-investigators: **Dr Marie-Christine DURQUETY (ophthalmologist)**

15.06.11

Dr Clotilde TRARIEUX-FOURAULT (general practitioner)

14.06.11

Quality Assurance Personnel: **Danièle PICARD** 14.06.11

ANIOSAFE MANUCLEAR NPC HF

Données de biodégradabilité

Biodegradability data

Matière inorganique 89.9 % [1]

Inorganic material

Non concerné par la notion de biodégradabilité

Not concerned by biodegradability notion

Matière organique biodégradable [2] 10.1 % [1]

Biodegradable organic material [2]

Substances facilement biodégradables et/ou intrinsèquement biodégradables[3]

Readily biodegradable substances and/or inherently biodegradable [3]

Matière organique non biodégradable ou sans données de biodégradabilité [2] 0 % [1]

Non biodegradable organic material or material without any biodegradability data [2]

Substances ne remplissant pas les critères de biodégradabilité, ou substances pour lesquelles aucune donnée de biodégradabilité n'est disponible.

Substances which not fulfil the biodegradability criteria, or substances without any biodegradability data.

Conclusion

Conclusion

ANIOSAFE MANUCLEAR NPC HF contient 100 % de matières inorganiques et de matières organiques biodégradables.

ANIOSAFE MANUCLEAR NPC HF *contains 100% of inorganic material and of biodegradable organic material.*

[1] % p/p indicatif */ indicative w/w %*

[2] Données de biodégradabilité communiquées par les fournisseurs des matières premières utilisées pour la formulation du produit et disponibles à la date du présent document / *Biodegradability data on raw material used for product formulation, provided by our suppliers and available at the date of this document*

[3] Selon les lignes directrices OCDE 301 et 302 / *According to 301 and 302 OCDE guidelines*

1921_FR-EN_05-09-18