



RAW MATERIAL IDENTIFICATION DATA :
SEPIGEL 305
Re : : C/0544/GB/11/NOVEMBER 2004

- ◆ **Commercial name :**
SEPIGEL 305
- ◆ **Manufacturer (address, telephone, fax, person to contact) :**
SEPPIC - Usine Lacaze Basse - BP 228 - 81105 CASTRES CEDEX France
- ◆ **Supplier (address, telephone, fax, person to contact) :**
SEPPIC - 75 Quai d'Orsay - 75321 Paris 07 - France
Tel : (1) 40 62 55 55
Fax : (1) 40 62 52 53
Michel Boyer : Sale Cosmetic Manager
- ◆ **Raw material category :**
Thickening - emulsifying agent
- ◆ **Chemical name (IUPAC), formula :**
Polymer in inverse emulsion
- ◆ **INCI name :**
Polyacrylamide and C13-14 isoparaffin and laureth 7
- ◆ **EINECS number / ELINCS number (add explanatory note if left blank) :**
Polymer not concerned
- ◆ **Cas number :**
38193-60-1 / 64742-47-8 / 3055-97-8
- ◆ **For dyes : colour index number (C.I. number) :**
- ◆ **For dyes : Colipa number :**
- ◆ **Registration status (EC, USA, Japan) :**
 - For cosmetic use : no specific restriction in EU, US and Japan
 - For quasi-drug use : authorized in Japan : MHW-KYS.04.C (92.05.29)
 - US - pesticide formulations : acceptable for use as inert ingredient in non food use pesticide formulation (EPA Statement, 07/2004)



MANUFACTURING PROCESS DATA

- ◆ **Source of the starting material :**
- ◆ **Is the substance of vegetable origin ? (if necessary give details) : No**
- ◆ **Is the substance of animal origin ? (details of the animal species) : No**
If obtained from cattle, sheep or goats, state number of points reached in accordance with the recommendations of the Federal Health Office of 9 May 1994 (determination of user safety)
- ◆ **Is the substance of neither vegetable nor animal origin ? (if necessary give details) :**
Synthetic origin
- ◆ **Description of the manufacturing process (if necessary attach as appendix) :**
Polymerisation in inverse emulsion
- ◆ **Is the manufacturing process likely to give rise to residues, eg of solvents or catalysts ? Type and concentration ?**
No

RAW MATERIAL SPECIFICATION DATA

- ◆ **Active substance content :**

45-49 % (dry extract)

- ◆ **Composition :**

| | |
|---|----------|
| Acrylamide/sodium acryloyldimethyltaurate copolymer | 35-45% |
| C13-14 isoparaffin | 15-25% |
| Laureth-7 | 3-8% |
| Water | qsp 100% |

- ◆ **Additives / auxiliaries :**

- ◆ **Type of preservatives (%) :**

No

- ◆ **Antioxidants (%) :**

No

- ◆ **Solvents (%) :**

Water

- ◆ **Other additives (%) :**

- ◆ **Secondary constituents and any trace impurities, type and concentration (should there no data on individual points, please state "no data available") :**

- ◆ **1.4-Dioxane :**

No

- ◆ **Ethylene oxide :**

No

- ◆ **Solvent residues (benzene, ...) :**

No

- ◆ **Monomers :**

Monoacrylamide \leq 2 ppm

- ◆ **Free amines**

No

- ◆ **Nitrosamines :**

No

- ◆ **Heavy metals (lead, cadmium, mercury, antimony, arsenic, chromium, silver, cobalt, nickel) :**
 - < 10 ppm
- ◆ **Pesticides (α -, β -, γ -HCH, DDT, DDE, dichlofenthion, PCBs) :**
 - No
- ◆ **Analytical data (please attach as appendix) : See attach appendix 1**
- ◆ **Analytical data on the raw material (analytical methods, detection limits) :**
- ◆ **Analytical data on the impurities (analytical methods, detection limits) : See attach appendix 1**
- ◆ Sepigel TM305 does not contain any substances mentioned in the “List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down” from annex III – Part 1 completed by the directive 2003/15/EEC.

TOXICOLOGICAL DATA

Please attach details of the method used, the animal species and the test concentration as original product and, where applicable, available scientific literature (eg database research) as an appendix.

- ◆ **Mucous membrane irritation data (eye irritation) :**
 - Non irritating at 2 % according to HET-CAM method (SEPPIC Expert Report 298)
 - Non irritating 3% according to RBCA method (SEPPIC Expert Report 862)

♦ **Data obtained in human studies on skin irritation :**

The tolerance of SEPIGEL 305 has been assessed according to different methods.

• **Repeated applications** (under semi-occlusive conditions)

The tolerance of a 5% dilution **SEPIGEL 305** gel was assessed by repeated applications on healthy volunteers.

Area tested : inside of the elbow (interesting because it is a maceration area similar to semi-occlusive conditions).

Number of volunteers : 12

Duration of treatment : 42 days

Number of applications per day : 2

After 42 days, there was no erythema and no irritation. Under these test conditions a 5% **SEPIGEL 305** dilution shows **perfect tolerance**. (ISPE experts report 279/92)

• **Single application** (under semi-occlusive conditions)

The tolerance of a 5% **SEPIGEL 305** gel was assessed by a single application using a semi-occlusive patch test over 48 hours on healthy volunteers. Under the test condition, 5% **SEPIGEL 305** in water demonstrates **good tolerance** (experts reports IEC 50214D/CN50205).

• **Single application** (under occlusive conditions)

1 - Vehicule : water

When tested using an occlusive patch test, **SEPIGEL 305** gels have similar behavior to that of volatile fatty phases (volatile silicon oils for example). In fact, under these conditions the isoparaffin present in **SEPIGEL 305** can not volatilize naturally, this means that the isoparaffin is forced to penetrate the skin causing slight erythema. To avoid this phenomenon, the distribution coefficient of the isoparaffin should be modified by adding, for example, to **SEPIGEL 305** gel, a non volatile fatty phase in equivalent quantity (paraffin oil, ester for example). The isoparaffin thus solubilized cannot cause erythema. The tolerance of the cream gel produced in this way is **excellent** (Experts reports : BIOGIR 92-1030/BIOGIR 92-1031/BIOGIR 92-1032/IEC R50216D/BIOGIR 95-19/BIOGIR 95-25/BIOGIR 95-29.)

Vehicule : paraffin oil

When tested using an emulsion patch test, SEPIGEL 305 at 5% dilution in liquid paraffin oil show a **perfect tolerance** (Expert report IEC)

2 – Study on Polish skin (recognized as particularly sensitive) – 48 hours occlusive patch test – 50 volunteers.

Product tested is considered as non-irritant for the skin : no significant irritation or intolerance reaction (Expert report PERITESCO PO 1323/DLCE 99172 C)

♦ **Data obtained in human studies on sensitization :**

(See Report : IEC R41131 D)

Clinical study for the evaluation of the irritating and sensitizing potentials of SEPIGEL 305 in a 5% dilution (V/V), in a mixture composed of 10% liquid paraffin and distilled water according to Marzulli-Maibach method in 50 healthy adult volunteers.

Induction period

9 consecutive applications, to the same area, of about 0.02 ml, per volunteer, of SEPIGEL 305 in a 5% dilution as described, by the occlusive epicutaneous route (Finn Chamber) for about 48 hours to the skin of the arm of 50 volunteers.

Rest period

15 days without any application.

“ Challenge ” Phase

Simple application of about 0.02 ml per volunteer, of the test product, by the epicutaneous occlusive route for about 48 hours, to the skin of the back .

Results

In conditions test, the test product did **not provoke any primary or cumulative irritation, nor any sensitization reaction.**



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EC SAFETY DATA SHEET

See MSDS enclosure

Document approved on November 2004
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