

Gendocs



PROJECT NAME (Ingredient Trade Name): Human epidermal growth factor, hEGF Active Ingredient Scientific Name: Submission Date: 2011. 3. 4

Description of Product: Human epidermal growth factor produced in recombinant yeast

## 1. Supporting Evidence (Efficacy/Functionality):

Provide all supporting literature and research studies, publications, protocols, and analytical assessment.

Please separate data into:

Mechanism of Action/s (MOA):

hEGF initiate signaling cascade by binding to the EGF receptor located in the membrane. hEGF promote the growth of fibroblast which synthesize collagen, resulting in regeneration of skin and reduction of wrinkles. hEGF is registered to INCI and used as a functional ingredient for wrinkle care.

• Chemistry/Characterization data:

GD-EGF(Trade name) : 53aa(exact copy of hEGF) GD-EGFplus(Trade name) : 90aa(hEGF 53aa + fusion partner 37aa)

o In vitro bioassay data:

*In vitro* activity and the concentration of GD-EGF and GD-EGFplus were determined by using the commercial ELISA kit(EGF immunoassay kit, invitrogen)



• In vivo testing :

EGF activity assay (Western blot analysis)



The effects of GD-EGF on the phosphorylation of signaling proteins were compared to that of commercial hEGF produced in *E. coli*. Phosphorylation was increased to proportional to the concentration of hEGF in both cases.



## Collagen Assay(Sircol assay)



Cell Growth Assay(MTT assay)



The effects of GD-EGF and GD-EGFplus on the cell growth and synthesis of collagen were compared to that of commercial hEGF produced in *E. coli*. GD-EGFplus was more effective than GD-EGF in both cases.

o Clinically tested : not tested

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- Provide studies done by Company on the ingredient.
- Total number of clinical studies completed?
- Study design? (number of subjects, duration of the study/ies, double-blinded, placebocontrolled, case controlled, etc.)
- Percent response rate?
  - Dose and delivery form used in the study/ies
- Published or not published, and in which journal/s: in preparation
- Recommended Delivery form/s: Powder or liposome
- Recommended dose/s? (mg per day)
- o Collaborating Organizations, professors or University Affiliations :
  - Dr. Jung-Hoon Sohn, Industrial Biotechnology and Bioenergy Research Center, Korea Research Institute of Bioscience and Biotechnology
- o Conclusions from the studies: not determined



## 2. Intellectual Property / Exclusivity

Provide an IP Portfolio summary to include:

- Provide patent information
  - Provisional/non-provisional/PCT/: non-provisional
    How is the patent upique, compared to competition
    - How is the patent unique, compared to competition? -Low production cost : High yield and simple purification procedure -Safety : GRAS host organism, no endotoxin
  - Number of patents? one
  - Patent Type? : Application
  - Patent Number/s, title, abstract, claims and application/issue dates
    -Patent number : 10-2010-0109441

-Title : A method for production of human epidermal growth factor using protein fusion techniques in yeast

-Abstract : A novel fusion partner originated from yeast Saccharomyces cerevisiae was applied to enhance the secretion yield of hEGF protein and to simplify the purification process in yeast and yeast strain was engineered to protect truncation of recombinant proteins

-Claim : A method for production of human epidermal growth factor with HL peptide originated from VOA1 gene

-Issue date : 2010. 11. 04

o Describe exclusivity options (MLM, all markets, global, etc.)