# Regulatory Information for HYDROVANCE®

## INCI Composition

The values given below are typical.

| INCI Name | CAS N° | EINECS N° | Concentration | Function |
|---|---|---|---|---|
| Hydroxyethyl urea/urea,N,N' Hydroxyethyl | 1320-51-0 | 215-304-0 | 36-43% | Moisturizing agent |
| Aqua | 7732-18-5 | 231-791-2 | <55% | Solvent |
| **Residuals** | | | | |
| Urea | 57-13-6 | 200-315-5 | <3.0% | Residual material |
| Ethanolamine | 141-43-5 | 205-483-3 | <0.5% | Residual material |
| Ammonium lactate | 515-99-0 | 208-214-8 | <2.0% | From neutralization with lactic acid |
| N,N'bis(2-hydroxyethyl urea) | 15438-70-7 | | <5.0% | Reaction by product |
| 2-oxazolidone | 497-25-6 | 207-840-9 | <1.0% | Reaction by product |
| Diethanolamine | 111-42-2 | 203-868-0 | <0.025% | Residue from ethanolamine |

## Manufacturing Statement

Hydroxyethyl urea is manufactured by reacting ethanolamine with excess urea. The product HYDROVANCE® is prepared by diluting the hydroxyethyl urea with water and neutralizing the excess ammonia generated in the reaction with lactic acid.

## CMR Statement

The active ingredient in HYDROVANCE® hydroxyethyl urea is manufactured from synthetic raw materials of petrochemical origin. HYDROVANCE® is not known to contain detectable levels of CMRs.

## Allergen Statement

HYDROVANCE® is not known to contain any of the 26 allergens listed in the 7th amendment to the EU Cosmetic Directive 76/678/EC as Items 67-92 in Annex III of the Directive and of Regulation (EC) 1223/2009 on cosmetic products. The listed allergens are not added as deliberate ingredients or as ingredients in the raw materials used in their manufacture.

## Animal Testing Statement

The original animal testing was carried out on the hydroxyl ethyl urea ingredient in this product ending in July 2001. This testing was for none cosmetic use of the product. At that time there were no validated none animal alternative tests available.

During October 2007 an acute inhalation study was carried out on HYDROVANCE® Moisturizing agent. This study was carried out in the US at a suitable authorized contract testing laboratory. The study followed a protocol compatible with B.2. ACUTE TOXICITY (INHALATION), the actual protocol is US EPA OPPTS 870.1300 which is harmonised with OECD 403. There are currently no valid none animal alternative test methods available for assessing the acute inhalation hazard of cosmetic ingredients.

## 1,4 Dioxane Statement

HYDROVANCE® is entirely synthetic polymer derived from petrochemical based raw materials, there is not information to suggest that this product would contain any levels of 1,4 dioxane.

## Dioxins Statement

HYDROVANCE® is not known or expected to contain dioxins based on the available information on the raw materials used in its manufacture and the manufacturing process. However we have not analysed this product for the presence of dioxins.

SE-444 85
Stenungsund
Sweden

T +46 303 85 000
F +46 303 770 281
www.akzonobel.com/sc

**Formaldehyde Statement**
HYDROVANCE® does not contain any formaldehyde or formaldehyde releasing chemicals as deliberate ingredients or known to be present in the raw materials used in its manufacture.

**GMO Statement**
HYDROVANCE® is entirely synthetic derived from petrochemical based raw materials, there is not information to suggest that this product would contain any levels of GMO derived substances.

**Gluten Statement**
HYDROVANCE® contains no plant derived materials it is entirely synthetic polymer in water and therefore no gluten would be expected to be found in this product.

**Heavy Metals Statement**

| Test | Result |
|---|---|
| Lead (Pb) | Not detected <10 ppb |
| Arsenic (As) | Not detected <10 ppb |
| Cadmium (Cd) | Not detected <10 ppb |
| Mercury (Hg) | Not detected <10 ppb |
| Chromium (Cr) | Not detected <10,2 ppm |
| Nickel (Ni) | Not detected <0,08 ppm |
| Beryllium (Be) | Not measured but not expected |
| Cobalt (Co) | Not detected <10 ppb |

**BSE Statement**
HYDROVANCE® Moisturizing Agent is manufactured in the USA from synthetic reactants which are derived from petrochemical based raw materials. HYDROVANCE® Moisturizing Agent contains no animal derived materials and therefore no material of bovine, ovine or carpine origin or any specific risk materials as defined in Commission Regulation (EC) 999/2001. There is therefore no risk from Bovine Spongiform Encephalopathies (BSE)/ Transmissible Spongiform Encephalopathies (TSE), associated with this product.

**Nanomaterial Statement**
HYDROVANCE® does not contain any nanomaterial according to the definition in the EU Cosmetic Regulation (EC) No 1223/2009 or Commission Recommendation, of 18 October 2011 on the definition of nanomaterial (2011/696/EU).

**Parabens Statement**
HYDROVANCE® does not contain any Isobutyl parabens or Isopropyl parabens as deliberate ingredients or known to be present in the raw materials used in the manufacture.

**Pesticides Statement**
As HYDROVANCE® is derived from synthetic raw materials it is not expected to contain detectable levels of pesticides.

**Residual Solvents Statement**
HYDROVANCE® does not contain any organic solvents as deliberate ingredients.

Sincerely,



**Marika Johannesson**
Manager Product Stewardship and Regulatory Affairs EMEIA