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C.F. e PARTITA IVA 00098610330
CAP. SOC. EURO 2.000.000 I.V.
R.I.PC 032-1483
R.D.PC 44507
MECC EXPORT PC002237

azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **IDROSSIETILCELLULOSA ALTA VISCOSITA'**

NOME INCI Hydroxyethylcellulose
NOME INCI USA Hydroxyethylcellulose
CAS 9004-62-0

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Identificazione IR		conforme	
Umidità		<=6,00	%
Viscosità 1%, 25°C		1.500 - 2.500	cPs
pH		6,00 - 8,50	
* Granulometria su 425 micron		<=10,0	%
Revisione Capitolato		2	
Data Approvazione		28/11/2014	

* saggi non obbligatori

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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HYDROXYETHYLCELLULOSE HIGH VISCOSITY is a nonionic water-soluble polymer derived from cellulose. It is a nonionic cellulose ether, and its solutions are unaffected by cations. Natrosol properties and functions make it suitable for use in a broad range of cosmetic and toiletry applications. Natrosol HYDROXYETHYLCELLULOSE HIGH VISCOSITY has a uniform grain appearance and makes water white solutions. Many grades are available based on molecular substitution, viscosity, and particle size.

Origin Information: HYDROXYETHYLCELLULOSE HIGH VISCOSITY is a synthetic polymer derived from plant origin. HYDROXYETHYLCELLULOSE HIGH VISCOSITY is derived from cellulose, the most abundant polymer in nature. HYDROXYETHYLCELLULOSE HIGH VISCOSITY is manufactured using highly purified cellulose pulp, which is made from soft wood trees (such as pine) and/or cotton linters, which is derived from the short cotton fiber removed from cotton seeds during the cotton seed oil production. This cellulose is treated with synthetic chemicals to obtain the properties of the desired HYDROXYETHYLCELLULOSE HIGH VISCOSITY polymer. This polymer is inert and highly purified with virtually no odor or color.

Description of Manufacture: HYDROXYETHYLCELLULOSE HIGH VISCOSITY is a cellulose ether, produced by reacting alkali cellulose with ethylene oxide (EO) under rigidly controlled conditions. The structure of the cellulose molecule can be visualized as a polymer chain composed of repeating cellobiose units. These, in turn, are composed of two anhydroglucose units (ß-glucopyranose residues). Each anhydroglucose unit contains three hydroxyl groups. By substituting hydroxyethyl groups (straight chain) for some of the hydrogens of these hydroxyls, hydroxyethylcellulose is obtained. The hydroxyl groups substituted per anhydroglucose unit is known as the “degree of substitution,” or D.S. If all three hydroxyls are replaced, the maximum theoretical D.S. of 3.0 (impossible in practice) would result. Substitution can also occur when ethylene oxide reacting at previously substituted hydroxyls, can polymerize to form a side chain (branching). The average number of moles of ethylene oxide that become attached to each anhydroglucose unit in cellulose, in the two ways described, are called moles of substituent combined, or M.S. (Molecular Substitution). M.S. is the typical analysis performed for Natrosol HYDROXYETHYLCELLULOSE HIGH VISCOSITY and not D.S. In reacting ethylene oxide with cellulose to form the hydroxyethylcellulose ether of cellulose, solubility in water is achieved as the degree of substitution is increased. By selecting appropriate reaction conditions and moles of substituent, complete and quick solubility in water is obtained. Natrosol 250, which has optimum solubility in water, has an M.S. of 2.5 (5 ethylene oxide groups / 2 units) and a D.S. of 1.5 (3 hydroxyls substituted / 2 units).

Food Contact Regulatory Status: Natrosol and Natrosol R-grades are included in the list of materials that are in compliance with requirements of the U.S. Food and Drug Administration for use in adhesives and in resinous and polymeric coatings employed on the food-contact surfaces of metal, paper, or paperboard articles, and other suitable substrates intended for use in food packaging as specified in the U.S. Code of Federal Regulations, 21CFR subject to the limitations and requirements of each regulation under the following sections: 175.105, 175.300, 176.170, and 176.180, 177.1200, and 177.1400.

Compendial Compliance: Natrosol personal care grades are neither tested for, nor is compliance claimed to, any specific compendium.

Glyoxal - European Dangerous Substance Directive (67/548/EEC: 79/831;EEC) and Carcinogen/ Mutagen/ Reproductive Toxicant Directive: Glyoxal is used in Natrosol™ R-types to improve dispersibility in water and reduce dissolution time. Glyoxal is a processing aid and does not need to be reported on the cosmetic ingredient label. On 15 February 2008 the updated Cosmetic Directive 2008/14/EC was published in the Official Journal. Part 1 of Annex III to Council Directive 76/768/EEC was amended in accordance with the Annex to Directive 2008/14/EC to allow glyoxal, CASRN 107-22-2, EINECS No. 203-474-9 at a maximum

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authorized concentration of 100 mg/kg (ppm) in the finished cosmetic product. Formulations in which Ashland polymers are used at typical levels of 1% will be below the maximum authorized concentration of 100 mg/kg.

Residual Solvents: Based on analyses of other grades for residual solvents due to regulations in those industries, the following are typical values. We do not test personal care grades but would expect comparable results. Acetone and isopropyl alcohol (IPA or 2-propanol) are used in the manufacture of HYDROXYETHYLCELLULOSE HIGH VISCOSITY. Residual acetone is less than 500 ppm (<0.05%) and isopropyl alcohol is less than 10 ppm (0.001%). HYDROXYETHYLCELLULOSE HIGH VISCOSITY may contain trace amounts [<500 ppm (<0.05%)] of tertiarybutylalcohol (TBA).

Volatile Organic Compounds (VOCs)/Hazardous Air Pollutants (HAPs): We do not analyze the VOC or HAP content of hydroxyethylcellulose either to the EPA Method 24 or the EU Council Directive 1999/13/EC, Regulation 1882/2003 or Directive 2004/42/EC.

California PROP 65: The State of California, Environmental Protection Agency, Office of Environmental Health Hazard Assessment, Safe Drinking Water and Toxic Enforcement Act of 1986 lists chemicals, (updated at least once per year), known to the State to cause cancer or reproductive toxicity. We neither use nor have any reason to suspect that any non-naturally occurring chemical substances listed under this legislation are present in this product. As a consequence, with the exception of lead and cadmium, we do not test for their presence. Lead and cadmium are not used in the process, but we assay for them as part of our routine testing program for heavy metals. Values are always well below the limits for lead and cadmium, as described in the specifications.

BSE/TSE Information: These are plant-based products, and we neither use nor have any reason to suspect that these products come into contact with or contain bovine, caprine or ovine-derived materials or chemicals in either the components or the process used for manufacture, nor do they come in contact with animal products during storage or shipment. As such, there is no concern about these products containing BSE (Bovine Spongiform Encephalopathy)/TSE (Transmissible Spongiform Encephalopathies) specified risk material as defined in the European Commission Decision 97/534/EC and EMA/410/01.

CMR substances: With respect to EU Regulation 1272/2008/EC (Classification, Labelling and Packaging of Substances and Mixtures), European Cosmetics Regulation (EC) 1223/2009 and Directive 76/768/EEC including all amendments, the EU has developed a list of CMR substances which is divided into several categories. This list, linked to the Dangerous Substances Directive, is updated at regular intervals. Based on this list, the Cosmetic Directive 1223/2009/EC has been updated. Regarding Cat. 1B substances, ethylene oxide (EO) is used in the manufacture of Natrosol™ hydroxyethylcellulose (HYDROXYETHYLCELLULOSE HIGH VISCOSITY) and Polysurf™ modified HYDROXYETHYLCELLULOSE HIGH VISCOSITY but the residual EO in these products is <1 ppm. Regarding Cat. 2 substances, Natrosol 250 R-types only may be treated with glyoxal (CAS RN 107-22-2, Mut. Cat. 2) for better management of dissolving properties. Glyoxal has been approved for use in cosmetic products, not to exceed 100 ppm in the cosmetic product. The use of these materials is technically unavoidable.

Allergens/Hypersensitivities: We do not intentionally add any of the substances included below. Zwijndrecht maintains dedicated manufacturing facilities for these products and neither uses, nor has any reason to suspect that these products (or any component of these products) comes into contact with, the substances below. Also, manufacture, storage and distribution are performed in a highly controlled manner to avoid contact with any foreign substances including those listed below. These products do not require labeling with reference to EU Regulation 1223/2009/EC (cosmetic regulation). These products meet the requirements of the U.S. Food and Drug Administration Food Allergen Labeling and Consumer Protection Act of 2004.

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Antioxidants	Artificial color/flavor
Artificial sweeteners	Benzoic acid and products thereof
Bee pollen	Beef and beef derivatives
Butylated hydroxyanisole (BHA)	Carrots
Casein	Cereals containing gluten and products thereof
Chocolate/Chocolate Derivatives	Cinnamon
Cocoa and products thereof	Coconut Coriander
Corn and products thereof	Crustaceans and products thereof (including shrimp)
Dyes or Azo colors including tartrazine	Eggs and products thereof
Environmental Hormones (including alkylphenol or derivatives)	FD&C Colors or dyes Fish and products thereof
Fruits	Gluten
Grains (wheat, rye, oats, barley, spelt, malt or any derivative thereof)	Hydrolyzed Animal or Plant Proteinq
Iodine	Latex
Legumes (including soybeans and products thereof)	Lupine and products thereof
Milk and products thereof (including lactose)	Mollusks and products thereof (including snails, clams, octopus, squid, etc.)
Monosodium Glutamate/Glutamates	Mustard and products thereof
Natural color/flavors	Nuts and products thereof
Peanuts and products thereof	Pork & pork derivatives
Preservatives (including benzoic acid salts and esters, sorbic acid salts and esters, sulfites)	Rice Seeds and/or oils and products derived from (canola, poppy, safflower, sesame, sunflower, etc.)
Sodium (elemental) Starch Sugar (sucrose, maltose, dextrose, glucose, etc.)	Sulfur dioxide and sulfites @ concentrations >10 ppm as SO2
Tertiary Butylhydroquinoe (TBHQ) Tocopherols	Tree Nuts or Other Nuts and/or oils and products derived from (walnuts, cashews, almonds, pistachios, etc.)
Vanilline	Vegetables (including celery & Umbelliferae family)
Yeast (Autolyzed)/Yeast extract	

EU Cosmetic Regulation 1223/2009/EC, 76/768/EEC and Amendments and IFRA Fragrance Ingredients: These products do not contain the following chemicals listed in the Cosmetics Directive or the current IFRA Fragrance Ingredients list in either the raw materials, the manufacturing process or the finished product. These products do not come in contact with any of the listed chemicals during packaging or storage prior to delivery to the customer. None of these products require labeling with reference to these Directives. We do not test for these chemicals. For a complete list of IFRA fragrance ingredients please refer to:

Alpha-Isomethyl Ionone	Amyl Cinnamal	Amylcinnamyl Alcohol
Anise alcohol	Benzyl Alcohol	BenzylBenzoate
Benzyl Cinnamate	Benzyl Salicylate	Butylphenyl Methylpropional
Cashmeran	Cinnamal	Cinnamyl Alcohol
Citral	Citronellol	Coumarin
Diethylphthalate	Dibutylphthalate	Dimethylphthalate
Diethylhexylphthalate	Other Phthalates	Eugenol
Evernia Prunastri (Oakmoss)	Extract	Evernia Furfuracea (Treemoss)
Extract	Farnesol	Furfural
Gamma Butyrlactone	Geraniol	Geranyl Nitrile
Glycol Ethers	Hexyl Cinnamal	Hydroxycitronellal
Hydroxyisohexyl 3-Cyclohexene	Carboxaldehyde	Isoeugenol
Limonene	Linalool	Methyl 2-Octynoate

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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Nitromusks	Polycyclic Musks	Natural Musk
Macrocyclic Musks	Camphor	Estragol
Eucalyptus Oil	Menthol	Methyleugenol
Methyl Octine Carbonate	Phenylacetaldehyde	Rose Crystals
Safrol	Tagetes Extracts & Oils	Thyme Oil
Total Aldehydes	Peru Balm & Derivatives	BHA
BHT	NTA	EDTANapthalene

Other Chemicals: We do not use nor has any reason to suspect that these products contain the followingchemicals either in the raw materials, the manufacturing process or finished product. Further, these products do not come in contact with these chemicals during packaging or storage prior to delivery to the customer.

3-MCPD (ref. European Council Directive 446/2001/EC)	Absorbable organic halogens (AOX)
Acetonitrile	Acrylamide
Aflatoxins	Alkyl phenol ethoxylates
Amines or their derivatives, including nitrosamines	Asbestos
Benz[a]pyrene	Benzoates or Benzoin
Boron or borates	Castor Oil
Colophony	Coniferyl Alcohol
Cyanuric acid	Diacetyl
Diethylene Glycol	Di(2-ethylhexyl) phthalate (DEHP, CAS# 117-81-7)
Dimethylfumarate	Dioxins
Formaldehyde (ref. EU ComDec 2001/59/EC)	Glycerin
Lanolin	Melamine
Palm Oil	Parabens
Propionic acid	Preservatives
Salicylic acid	Silanes
Talc	Tributyltin
Vegetable oil	

Bisphenol A diglycidyl ether (BADGE) (ref. European Council Directive 2001/61/EC)
Bisphenol F diglycidyl ether (BFDGE) (ref. European Council Directive 2001/61/EC)
NOvolac glycidyl ether (NOGE) (ref. European Council Directive 2001/61/EC)
Bromodiphenylethers (ref. EU Dangerous Substances Directive 76/769/EEC, Directive 2003/11/EC and EU Water Policy Directive Decision 2455/2001))
Methansulfonic acid and derivatives thereof (such as benezenesulfonic acid esters, tosilates, di-isetonates and methansulfonyl chloride) and other sulfonic acids
Nitrofen (2,4-dichloro-1-(4-nitrophenoxy)benzene, CAS# 1826-75-5)
Thiuram Mix (tetra methyl thiuram monosulfide, tetra methyl thiuram disulfide, tetra ethyl thiuram monosulfide (=disulfiram), dipenta methylene thiuram disulfide)

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GMO Information: HYDROXYETHYLCELLULOSE HIGH VISCOSITY products, the starting material can be wood pulp and/or cotton linters. Our suppliers have informed us that the wood pulp is not sourced from genetically modified organisms, however, to the best of our knowledge, no non-GMO varieties of cotton exist. Therefore, we can not guarantee the compliance of HYDROXYETHYLCELLULOSE HIGH VISCOSITY products as not genetically modified and not derived from a genetically modified organism as defined by the EC regulations 1830/2003/EC on labeling and traceability and 1829/2003/EC on genetically modified food and feed and any amending legislation.

Animal Testing: Throughout the years the industry in general, and the cosmetics and pharmaceutical industry in particular, have been using animal testing as a reliable and realistic alternative for testing on humans. To minimize inconveniences for the animals, many non-animal testing methods have been developed. Only a limited number of methods have been validated and approved as a partial substitute for animal testing. As long as there are no officially approved and validated full substitutes, or combination of alternative methods available, it is not possible to stop testing on animals completely. ASI conducts animal testing only if we can not avoid this and will use the minimum number of animals that can give us reliable and interpretable scientific data. We can, however, inform you that we have not conducted animal testing of our hydroxyethylcelllose products since 1990.

Organic Status: These products are not certified Organic under either the U.S. National Organic Program or European standards.

Pesticides: HYDROXYETHYLCELLULOSE HIGH VISCOSITY is manufactured from cellulose, which is obtained by a very thorough and aggressive cleaning process. Since most pesticides are fat soluble, possible remaining pesticides are removed with the fat. Manufacturing of cellulose derivatives is conducted in a chemically very aggressive and reactive environment. Therefore, we assume that possible remaining levels are destroyed during the process. Since we do not add pesticides to our products in any process stage and since it is not being generated, we believe that our products are free from pesticides. For that reason, we do not conduct pesticide analyses of our products.

Jatropha plant: ASI does not use or nor do our products contain glycerin, phorbol esters or any derivatives from the Jatropha plant in the raw materials or any finished products.

Aflatoxin: Aflatoxin is a mycotoxin produced by some strains of the fungus Aspergillus. Associated concerns relate to nuts, groundnuts, dried fruit and cereals. We do not conduct testing for aflatoxins but we would not anticipate any mycotoxins to be present in these products based on the origin and nature of our processing.

Irradiation: We does not irradiate any products and none of the raw materials used in the production of those products have been irradiated.

Heavy Metals: Our excipient grade cellulose derivatives are tested for heavy metals as part of our routine testing program for compliance to the relevant compendial specifications for heavy metals and any individual metals, e.g. As and Pb, if applicable to that product. In addition, samples taken at random have been analyzed for individual metals content. Values are always well below the monograph compendial limits for individual metals where specified and total heavy metals specifications. We have no reason to believe that the levels of residual metals in personal care grades of these cellulose derivatives are different than the excipient grades.