1. PRODUCT IDENTIFICATION

Trade Name: NEEM EXTRACT GDBN
Manufacturer: PROVITAL S.A.
Responsible for the Safety Assessment: Lourdes Mayordomo
Tf./Fax: 3493-7192350/7190294
Kind of Raw Material: Active Ingredient

2. PRODUCT COMPOSITION

Components Breakdown (INCI). Including actives, solvents, preservatives, antioxidants and other additives:

<table>
<thead>
<tr>
<th>[EU]</th>
<th>CAS</th>
<th>EINECS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqua</td>
<td>7732-18-5</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>200-289-5</td>
</tr>
<tr>
<td>Melia Azadirachta Leaf Extract</td>
<td>84696-25-3</td>
<td>283-644-7</td>
</tr>
<tr>
<td></td>
<td>90063-92-6</td>
<td>290-052-2</td>
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Preservatives

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<tbody>
<tr>
<td>Sodium Benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
</tr>
<tr>
<td>Potassium Sorbate</td>
<td>24634-61-5</td>
<td>246-376-1</td>
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PCPC [CTFA]

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Impurities:

- Heavy Metals (as Pb): Less than 20 ppm.
- Pesticides: No data available. Not expected to be found.

3. TOXICOLOGICAL INFORMATION

Data obtained in our own toxicological tests and/or bibliographical research

Animal testing:
This product has not been the subject of animal testing or retesting for cosmetic purposes by or on behalf of this company.

General information:
The following substances have the GRAS status ("Generally Recognized As Safe"): Glycerin (21CFR182.1320)
There is a CIR Final Report on Safety Assessment of Sodium Benzoate including all the toxicological data: IJT, 20(S3):23-50, 2001, reopened 06/10.
There is a CIR Final Report on Safety Assessment of Potassium Sorbate including all the toxicological data: JACT 7(6): 837-80, 1988, confirmed 04/06.

Classification according to Council of Europe (*):

*(1)- Non-recommended ingredients  (2)-Ingredients which could not be assessed (3) –Recommended ingredients

Cytotoxicity:
No data available.

Skin Irritation:
Glycerin (RTECS nºMA8050000): Draize Test in the skin of rabbit , 500 mg, 24 h, Mild

Skin Sensitization:
No data available.

Eye Irritation:
Glycerin (RTECS no.:MA8050000): Draize Test eye rabbit= 500 mg/24h, mild

Mutagenicity:
An ethanolic extract of neem leaves showed antimutagenic effect in freshwater fish, Channa punctatus evaluated by cytogenetic tests ( Sci Total Environ 2006, 364 (1-3):200-14)

Acute toxicity:
Neem leaves extract (RTECS nº CL7615500): LD50 p.o. mouse = 4570 mg/kg, LD50 s.c. mouse= 6.25 mg/kg
Neem, leaf and bark, methanol extract (RTECS nº QO2795000): LD50 p.o. mouse = 13 mg/kg
Acute and subacute toxicity studies have indicated no mortality with 2.5 g/kg dose of an aqueous extract of neem leaves in mice and no significant alterations in body or tissues weight, food and water intake, haematological profile and various liver and kidney function tests in rats when treated for 28 days with 1 g/kg dose of neem extract.(Indian J Physiol Pharmacol. 2006, 50(3):241-9)
Neem, methanol extract from leaves (RTECS nº: CL7617520): TDLo p.o mouse = 100 mg/kg
Glycerin (RTECS nºMA8050000): TDLo oral in human = 1428 mg/kg
Glycerin (RTECS nº MA8050000): LD50 in rat: p.o.=12600 mg/kg, i.p.=4420 mg/kg, s.c.=100 mg/kg, i.v.=5566 mg/kg, LDLo in rat i.m. =10 mg/kg, TDLo in rat i.m.=5 g/kg
Glycerin (RTECS nº:MA8050000): LD50 oral mouse= 4090 mg/kg, LD50 i.p. mouse= 8700 mg/kg, LD50 s.c. mouse= 91 mg/kg, LD50 i.v. mouse= 4250 mg/kg, LD50 oral rabbit= 27 gm/kg, LD50 i.v. rabbit= 53 gm/kg, TDLo i.m. rat= 4 mL/kg, TDLo i.m. rat= 4000 mg/kg

Subchronic and chronic toxicity:
Neem leaves extract (RTECS nº CL7615500): TDLo p.o. guinea pig = 10 g/kg/5D-C, TDLo p.o. mammal-domestic = 2800 mg/kg/56D-C, TDLo p.o. rat = 3500 mg/kg/7D-I
The oral administration of an aqueous neem leaf extract the dose of 100 mg/kg for 2 weeks caused no toxic effects and was considered safe. This product showed also protective effects against benzo-a-pyrene induced carcinogenesis. (Indian J Biochem Biophys, 2007, 44 (4):209-15)
Acute and subacute toxicity studies have indicated no mortality with 2.5 g/kg dose of an aqueous extract of neem leaves in mice and no significant alterations in body or tissues weight, food and water intake, haematological profile and various liver and kidney function tests in rats when treated for 28 days with 1 g/kg dose of neem extract.(Indian J Physiol Pharmacol. 2006, 50(3):241-9)
Glycerin (RTECS no:MA8050000): TDLo oral rat= 96 gm/kg/30D-I, TDLo oral mouse= 560 gm/kg/8W-C, TDLo oral mouse= 2800 mg/kg/25W-C

Reproductive effects:
Glycerin:(RTECS nº MA8050000) rat, i.t. TDLo = 280 mg/Kg, 2 Days, male ; rat o. TDLo=100 mg/Kg, 1 Day, male ;rat, i.t., TDLo=862 mg/Kg, 1 Day, male
4195100G – NEEM EXTRACT GDBN

Version: 21 - 02/12/2011

Other data:

4. ECOLOGICAL DATA

Biodegradability:
Glycerin (HSDB nº492,Revision:20050624).Activated sludge test:220 mg/l resulted in a COD of 97%;Test in a 5 days: BOD= 82%. Glycerin is considered a substance easily degraded

Aquatic Toxicity:
The 24 h LC 50 of neem leaf extract for juveniles fish Prochilodus lineatus was estimated as 4.8 g/L (Comp Biochem Physiol C Toxicol Pharmacol, 2007, 145(2):236-44)
Glycerin: Inhibition multiplication test in algae (Microcystis aeruginosa) and protozoa (Entosiphon sulcatum) Toxicity threshold=2900 mg/l and 3200 mg/l (HSDB nº492,Revision:20050624)
Glycerin (HSDB nº492,Revision:20050624):LC50 goldfish > 5000 mg/l/24 h

Other data:
No data available.

5. CONCLUSION
The components of this product have registered adverse effects neither in its traditional uses nor in the historical marketing of this company. These data and the available toxicological information lead to the conclusion that the use of this product, under the normal conditions of cosmetic use and at the maximum recommended concentration, involves no risk for consumers.