BACKGROUND & OBJECTIVES
Excess cerumen remaining in the ear may impede ventilation, prevent drainage of normal secretion, provide a medium for microbial growth and harbour fatty acids irritant to the canal lining.

The cleansing efficiency of any solution depends on:
- ability to spread and be adsorbed on surfaces (adsorption or wetting power) for greasy dirt detachment,
- cerumen dissolution (emulsification) properties, to disperse dirt and debris.

RESULTS
Macroscopic observations (fig. 1)
- Before agitation, all 5 solutions remained clear while cerumen adhered to the tube walls.
- After 10 seconds agitation:
  ✓ Distilled water and Cerulane®: no detectable changes.
  ✓ Otolane®: turbidity with homogenous dispersion of cerumen.
  ✓ Otolane®: partial opacity, some cerumen clearly detached from the tube walls and floating on the surface.
  ✓ Physiological Ear Cleanser®: completely white and opaque solution reflecting the formation of an emulsion.

Quantity of cerumen dissolved and wetting power (fig. 2)
Significant difference was detected between the ear cleansers for the quantity of cerumen dissolved (one-way ANOVA, p=0.033). Fisher’s least significance difference (LSD) multiple comparison procedure could not discriminate among ceruminolytic activities of distilled water, Cerulane®, Otolane® and Otolane®.

The Physiological Ear Cleanser® was the only test solution that demonstrated statistically greater ability for cerumen dissolution as compared to distilled water (p <0.05).

Distilled water, Otolane® and Cerulane® failed to demonstrate any significant wetting ability: more than 300 seconds were needed for the cotton discs to submerge in undiluted test solutions. Calculated wetting power values for Otolane® and Physiological Ear Cleanser® were similarly elevated and corresponded to those of reference surface-active non-ionic agents used in the human baby cosmetics industry.

MATERIALS & METHODS
Test solutions
- Physiological Ear Cleanser® (Virbac): micelles of non-ionic surfactants, EDTA, citrus extract
- Otolane® (TVM): chlorhexidine digluconate, acetic acid, neutral cleansing base
- Cerulane® (TVM): purified sea water

Cerumen dissolution assay
Artificial cerumen similar to natural canine cerumen (lipid composition, consistency, melting point) was produced, based on literature data (Table). One mL of each test solution was poured into haemolysis tubes containing 100 mg of synthetic cerumen. Contact time was 10 minutes at 37°C. Moderate agitation was then applied for 10 seconds to mimic in vivo application. Solutions were vacuum-filtered on filter paper and cerumen remaining in the tube or on the paper was weighed for subtraction from 100 mg. The experiment was repeated 5 times for each formulation.

Adsorption/wetting power assay
The ISO 8022 normalised method was implemented. Standardised cotton discs were immersed in test solutions and maintained by a special grip. Complete penetration of the solutions into the fabric was indicated by disk submersion. The products were first tested undiluted. If the time to disc submersion was <300 seconds, 3 subsequent dilutions were tested to enable prediction of the concentration necessary to obtain disk submersion in 100 seconds (wetting power index). Five measurements were performed for each concentration of test solution.

Table. Synthetic cerumen composition

<table>
<thead>
<tr>
<th>Lipids</th>
<th>Weight (%)</th>
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<tbody>
<tr>
<td>Lanolin</td>
<td>30</td>
</tr>
<tr>
<td>Palmitic acid</td>
<td>30</td>
</tr>
<tr>
<td>Myristic acid</td>
<td>10</td>
</tr>
<tr>
<td>Oleic acid</td>
<td>10</td>
</tr>
<tr>
<td>Linoleic acid</td>
<td>10</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>10</td>
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</tbody>
</table>

mg/ml (dissolved cerumen) g/l (wetting power)

Figure 1. In vitro cerumen dissolution test:
Above: cerumen suspended in test solutions (10 min, 37°C)
Below: after vortex agitation for 10 s

Figure 2. Mean quantity (± SD) of cerumen dissolved by the 4 ear cleansers. Associated wetting power index.

CONCLUSIONS
Under the conditions of this study, Virbac Physiological Ear Cleanser® was the only test solution to demonstrate both significant cerumen emulsifying and wetting properties. These synergistic characteristics suggest good overall earwax removal efficacy.

Formulation issues account for difference in product activity. The Physiological Ear Cleanser® incorporates 2 non-ionic surfactants that lower oil-water and solid-water surface tensions, favour liquid distribution on surfaces and produce earwax emulsification.

Good correlation was found in this study between macroscopic appearance of test solutions, results of the cerumen dissolution test and of the reference ISO wetting method. The cerumen dissolution tube test proved to be a practical and valuable model for evaluation of the cleansing power of ear solutions before in vivo trials.

5th WCVD
August 25-28, 2004 Vienna - AUSTRIA