DEKABEN BL

A welcome choice in a challenging world of preservation
Dekaben BL, a structural isomer of thymol, is an interesting preservative booster in a market where formulators of cosmetic products are searching for alternative ways of product protection.

Dekaben BL, which is a structural isomer of thymol, has a low odour, taste, a high stability and a favourable safety profile. Moreover, it is not a halogen-containing substance. These characteristics make Dekaben BL a highly accepted and desired preservative for skin-care cosmetics.

**MAIN PROPERTIES**
- HIGH EFFICACY AGAINST E.G. PSEUDOMONAS AERUGINOSA
- HIGH STABILITY
- FAVOURABLE SAFETY PROFILE
- LOW ODOUR AND TASTE
- NON-HALOGEN COMPOUND

**Structural relation to thymol**
Dekaben BL has a structural similarity to thymol. Thymol is a component which occurs in many plants. The most well-known source are several Thyme species. The essential oil of these plants species may contain up to ca. 60 % of thymol. Thymol has many beneficial characteristics, such as an antimicrobial action, although the desired activities of Dekaben BL exceed that of thymol. The structures of Dekaben BL and thymol are given below:

![Dekaben BL and thymol structures](image)

**Legislation**
Dekaben BL has a very broad approval, both with respect to geography (it is e.g. approved in Japan) and applications (leave on and rinse off). The legislative details are listed in Table 1.
**Efficacy**

Several studies have been done on the efficacy of Dekaben BL.

**Efficacy in cosmetics**

The efficacy of Dekaben BL has been shown in a challenge test in a model emulsion. This formulation, which contains 0.2 % of an organic acid, is tested in a challenge test with and without the presence of 0.1 % Dekaben BL, at a pH of ca. 5.5.

As expected there is a heavy growth of e.g. *Pseudomonas aeruginosa* throughout the whole study. With 0.1 % Dekaben BL however, *Pseudomonas aeruginosa* are eradicated at day 7 or before, showing the strong efficacy of Dekaben BL.

**Phenol coefficient**

The phenol coefficient refers to the bactericidal activity by a 5–10 min. contact. For *Salmonella typhi* and for *Staphylococcus aureus*, the phenol coefficient was 17, for *Escherichia coli* it was 19. This means the bactericidal effects of Dekaben BL appear at 1/17 – 1/19 of the concentration compared with phenol for the tested organism.

**Bactericidal effects on 60-second contact**

Pathogenic *Escherichia coli* O157:H7 (Vero-toxin producing strains) were placed into contact with Dekaben BL at concentrations of 1000, 2000 and 5000 ppm for 60 seconds. At 1000 ppm, the number of bacteria is reduced, and at 2000 and 5000 ppm, the bacteria were extirpated.

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**TABLE 1 LEGISLATIVE OVERVIEW OF DEKABEN BL**

<table>
<thead>
<tr>
<th>INCI NAME (EC, PCPC):</th>
<th>o-Cymen-5-ol</th>
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</thead>
<tbody>
<tr>
<td>EINECS no:</td>
<td>221-761-7</td>
</tr>
<tr>
<td>CAS no:</td>
<td>3228-02-2</td>
</tr>
<tr>
<td>Chemical name:</td>
<td>4-isopropyl-m-cresol</td>
</tr>
<tr>
<td>EC approval:</td>
<td>Regulation (EC) 1223/2009, Annex V, no 38, max. 0.1 % (all cosmetics)</td>
</tr>
<tr>
<td>Japan (cosmetics):</td>
<td>Leave-on and rinse-off products, including the use on mucous membranes: max. 0.1 %. For rinse-off products when not to be applied on mucous membranes: no legislative upper limit.</td>
</tr>
<tr>
<td>Japan (JSQI):</td>
<td>JSQI name: 'Isopropyl Methylphenol', component/standard code: 103132-51. Cat. 1 (Medicated soap, shampoo, conditioner, depilatory, etc.) max. 1.0 %, other categories (2 to 6) max. 0.1 %.</td>
</tr>
<tr>
<td>USA:</td>
<td>Cosmetic Ingredient Review: safe at concentrations of up to 0.5 %.</td>
</tr>
<tr>
<td>Australia:</td>
<td>AICS listed.</td>
</tr>
<tr>
<td>China:</td>
<td>IECSC listed. Listed in Inventory of Existing Cosmetics Ingredients China (IECIC), Final 2014 version. Chinese name: o-伞花烃-5-醇</td>
</tr>
</tbody>
</table>
Efficacy against pathogenic organisms
Dekaben BL has been used in the treatment against athlete’s foot. Dekaben BL has been confirmed by pharmacological and clinical studies to show strong bactericidal or antibacterial activities against parasitic microorganisms such as the Trichophyton (data of 134 clinical cases).

Antiviral activities
Actions on influenza virus have been confirmed at 200 ppm.

Minimum inhibitory concentration
The efficacy of a preservative is shown by the values of the minimum inhibitory concentrations (MICs). The values in comparison with a range of other preservatives, and the action of Dekaben BL against a range of organisms, is given in Table 2.

Applications
Cosmetic preservative
Dekaben BL is highly appreciated as preservative booster in cosmetic products. Typically, 0.1 % is used in Europe, which is the maximum authorised concentration. It is strongly advised to use additional preservatives (e.g. fungicides) to maximise the efficacy. Dekaben BL can be used to boost a variety of different preservatives, and to use Dekaben BL as an ‘active preservative’.

Dekaben BL in oral care
Dekaben BL is used in oral care, to fight periodontal disease. Periodontal disease is caused by biofilms, and as with all biofilms, they are very hard to eradicate. Often, mechanical scrubbing is the only option left. In the mouth, conventional brushing is not always effective in removing the biofilm in hard-to-reach areas between the teeth. In addition to daily brushing, other techniques should be applied. It is shown that this preservative shows the best penetration against oral biofilm.

The evaluation using Periodontitis Biofilm Model showed that it exhibits better anti-bacterial effect against oral biofilm compared to triclosan and cetylpyridinium chloride, also inside the biofilm (Lion Corporation, website).

Other uses
There are many examples of possible miscellaneous uses, worldwide, using Dekaben BL (not necessarily possible in Europe, because of different regulations, e.g. the Biocidal Products Directive). Industrial uses comprise disinfection of air-conditioners and rooms, or by treating fabrics to obtain an antibacterial, deodorant and antifungal effect. When fabrics are treated with solutions of Dekaben BL, a growth inhibition zone could be observed in tests using e.g. moulds or S. aureus.


**Safety**  
The safety of Dekaben BL is substantiated by a broad package of safety tests, confirming the safety of the product. A summary is given below:

**Acute toxicity**  
LD50 (oral) > 2.2 g/kg;  

**Skin irritation**  
No irritation at 0.1 and 1.0 % on either intact or abraded skin (rabbit).  
Primary irritation index (PII) 0.06 out of 8.0 (5 % in PEG-400, rabbit).  
PII 0.22 out of 4.0 (10 % in ethanol, 3 daily 24 h exposures, guinea pig).  
No reactions observed (0.5, 1.0, 2.0 and 4.0 % in 50 % ethanol, guinea pig).  
No irritation (0.1 % and 1.0 %, human, 24 h).  

**Eye irritation**  
No irritation in washed eye (1.0 %, rabbit). Some effects noted in unwashed eye after 1 and 4 h, but not observed after 24 h.  

**Skin sensitisation**  
Not sensitising, no reaction observed (2 %, guinea pig, maximization study).  
Not sensitising in a human RIFT test (nine 24 h exposures).  

**Mutagenicity**  
Not mutagenic in a test with *Salmonella typhimurium* and *Escherichia coli*.  

**30-day toxicity**  
Animals survived doses of 0.7 and 2.0 g/kg. At 0.7 g/kg no noticeable variations were observed in body weight or food consumption.  

**90-day toxicity**  
Rats were fed 10, 100, 1000, or 2000 mg/kg for 90 days. No deaths observed. In the highest dose group, body weight gain decreased, but increased after non treatment.  

**Photosensitisation**  
No evidence of photosensitisation is shown (guinea pigs, up to 2 %).  

**Absence of estrogen-like activity**  
Dekaben BL did not show a significative increase in MCF-7 cell proliferation (indicative of estrogenic activity) in the range of the concentrations tested (10-3 to 10-7 ppm). Positive control showed a clear increase in cell proliferation at 10-8 to 10-12 M).

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**TABLE 2**  
**MINIMUM INHIBITORY CONCENTRATION (MIC) VALUES OF DEKABEN BL:**

<table>
<thead>
<tr>
<th>GRAM-POSITIVE BACTERIA:</th>
<th>MIC (PPM):</th>
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<tbody>
<tr>
<td>Mycobacterium H2</td>
<td>50</td>
</tr>
<tr>
<td>Bacillus subtilis ATCC 6633</td>
<td>150</td>
</tr>
<tr>
<td>Bacillus fluorescens</td>
<td>100</td>
</tr>
<tr>
<td>Bacillus cereus</td>
<td>150</td>
</tr>
<tr>
<td>Staphylococcus aureus FDA 209P</td>
<td>150</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GRAM-NEGATIVE BACTERIA:</th>
<th>MIC (PPM):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli IFO 3301</td>
<td>200</td>
</tr>
<tr>
<td>Klebsiella pneumoniae IFO 13277</td>
<td>200</td>
</tr>
<tr>
<td>Vibrio parahaemolyticus IFO 12711</td>
<td>250</td>
</tr>
<tr>
<td>Salmonella typhimurium IFO 13245</td>
<td>200</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa IFO 3755</td>
<td>500</td>
</tr>
</tbody>
</table>
Dekaben BL is a valuable preservative with a broad approval and acceptance. It is a welcome option in the rapidly changing world of preservatives.

**Incorporation**

The water solubility of Dekaben BL is rather low. As with all preservatives, it is not advised to dissolve Dekaben BL in the fat phase when protecting emulsions. It is advised to make a premix of Dekaben BL in a suitable solvent (e.g. Propylene Glycol, Butylene Glycol, Phenoxyethanol or Benzyl Alcohol). The premix can be added to the final product after emulsification. It has to made sure that Dekaben BL is well dissolved in the product.

Dekaben BL has a characteristic tendency to precipitate as crystals. In formulations, crystals may precipitate a long time after preparation. Particular caution is needed in emulsified or solubilised preparations.

In the next Table, the solubilities are given for Dekaben BL.

<table>
<thead>
<tr>
<th>SOLVENT:</th>
<th>GRAMS OF DEKABEN BL PER 100 G SOLVENT:</th>
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</thead>
<tbody>
<tr>
<td>ethanol</td>
<td>45</td>
</tr>
<tr>
<td>isopropanol</td>
<td>40</td>
</tr>
<tr>
<td>propylene glycol</td>
<td>18</td>
</tr>
<tr>
<td>glycerin</td>
<td>0.1</td>
</tr>
<tr>
<td>liquid paraffin</td>
<td>0.01</td>
</tr>
<tr>
<td>water</td>
<td>0.015</td>
</tr>
</tbody>
</table>

Furthermore it is possible to prepare concentrated premixes in Phenoxyethanol before adding it to the product, e.g. as 15 or 20 % solution. More concentrated solutions of Dekaben BL in Phenoxyethanol (25 or 30 %) will crystallise too fast.

**Characteristics in use**

**Astringency**

Because Dekaben BL has mild astringency, it provides a pleasant feature when used in cosmetics.

**Stability**

Dekaben BL is characterised by a relatively high stability against air, light, temperature, and humidity. It retains its effects without marked degradation or discoloration.

**Incompatibility**

When Dekaben BL is used together with non-ionic surfactants or macromolecular compounds such as CMC, its bactericidal activity may be reduced as it is contained in or adsorbed on micelles of the surfactant: enhancement of the effect by agents such as EDTA2Na or substitution for anionic surfactants is needed.

**Products**

Dekaben BL has a long history of use. It is not only used as a preservative, but also as an active agent in e.g. toothpastes and anti-acne creams, especially in Japan. This underlines the multifunctional character of Dekaben BL.
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