

CERTIFICATE

No. Z2 05 01 24776 004

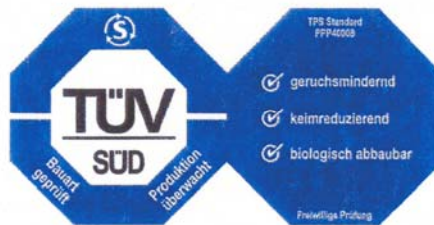


Product Service

Certificate Holder: **WESSO® AG**
 Martin-Luther-Straße 10
 91217 Hersbruck
 GERMANY

Production Facility: 24776

Test Mark:



Product: **Water and Air Hygiene Products**

Type: **WESSO® Air**

Data: concentrated solution in PE-cans
 of 5, 10, and 20 liters

Tested according to: PPP 40008:2004

The product was checked for compliance with basic requirements on a voluntary basis and is allowed to be shown with the test mark represented above. The following notice must be respected.

Study Report No.: 70083088

Valid before: 2010-01-12

Date, 2005-01-25



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Technical Report No. 70083088

Rev. 01

Date: 2005-01-11



Client: WESSO® AG
Martin-Luther-Straße 10
D-91217 Hersbruck

Production Facility: see above

Subject of Examination: WESSO® Air

Test Specification: TÜV Product Service test programme for water and air hygiene products
PPP 40008, 2004-11, Rev. 01

Study Demand: testing according to test specification

Study Result: The product WESSO® Air meets the applicable biological-toxicological requirements with respect to hygiene, effectiveness and safety of use.

WESSO® Air is effective in reducing unpleasant smell and germs, and it is biologically degradable.

Competence.
Certainty.
Quality.

This Technical Report must not be reproduced but as complete text. Use in marketing requires a consent statement in written form. The report includes the result of a single investigation with the product provided for testing and does not represent a generally binding decision on properties of current production.

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TÜV Product Service GmbH
TÜV SÜD Group

Munich Branch
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Germany

1 Device Description

1.1 Function

Producer information on use according to instructions:
The product WESSO® Air serves for the elimination of germs from air, and for that, the product is distributed by ultrasound (cold) air nebulizing in the air of closed spaces.



As nebulizers, devices may be applied which produce a steady stream of cold fog (aerosol) with particles of a size less than 5 µm.

WESSO® Air is utilized with well defined methods of active substance nebulizing, among others in food, medical devices and pharmaceutical industries, but also in public and private institutions.

Producer information on predictable misuse:

None

1.2 Technical Data

WESSO® Air is an aqueous concentrated solution containing agents in a concentrated solution (the exact recipe is known to the certification body) which for use will be diluted with completely desalted (deionized) water and nebulized cold by ultrasound at concentrations from 0,04-0,1 ml/m³ space.

The product is marketed in Lupolene cans of 5, 10, and 20 l content.

Shelf life amounts to 12 months.

The product is identified by the UBA (German Federal Environmental Agency) no. 12910302.

2 Order

2.1 Date of Order, Client Reference

2004-09-20

2.2 Receipt of Test Product Samples/Documentation

October 2004

2.3 Test Date

November 2004



3 Study Results

- WESSO® Air is defined as an agent eliminating germs from air, or as an active substance improving quality of air in closed spaces, respectively.
- The product is of importance as an additional and supporting measure in context of production hygiene. Based on a well established hygienic regimen and HACCP plan, microbiological hygiene of the environment can additionally be improved by applying WESSO® Air.
- Concomitant service consultations of the producer or contracted agents and the application of defined procedures are essential to ensure safety and suitability of use.
- Germ reduction up to bactericide properties was proved by competent expert reports. A germ reducing effect in the use as an agent eliminating germs from air also was confirmed by application accompanying verifications.
- Reports being in favour of it, based on analysis of applications in food industries, indicate that with the use according to the specified purpose in reported fields of utilization an improvement of production and environmental hygiene, respectively, is obtained by a reduction of germ pollution in the air of closed spaces. This again has a positive effect on product quality with respect to preservability and germ contamination.
- WESSO® Air is comparable to the product WESSO® Claris concerning its combination of active substance. In comparison, WESSO® Air contains much lower concentrations of the agents. Therefore, the results of the TÜV Bavaria-Institute for Safety in Biotechnology study from 1996-02-28 are transferable with respect to the properties biologically degradable and saving material.

- So far, damage to material in adequate use was not observed.
- There are no concerns about regulations on food law in view of the agents and concentrations applied.
- Toxicological and adverse effects in man could neither be assessed in expert statements nor be proved in test series and biological indicator testing (CMT: ciliate mobility test).
- WESSO® Air does not come under labelling regulations concerning additives.



3.1 Positive Study Results

WESSO® Air has smell and germ reducing effects and is biologically degradable.

The requirements according to test programme PPP 40008 Rev. 01 are met.

3.2 Items which are not in accordance with test specification

None

4 Annotation

- The actual laboratory analysis concerning the composition of the WESSO® Air stock solution must be handed in later.
- This study should be considered in context of the results of the production facility visitation.

4.1 Comment on production

At present, the production facility is relocated and should be inspected as late as the 1st quarter of 2005.

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5 Conclusion

The product WESSO® Air meets the applicable biological-toxicological requirements with respect to hygiene, effectiveness and safety of use.



TÜV PRODUCT SERVICE GmbH
MHS 2 - Non-active Medical Products

Project Manager

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