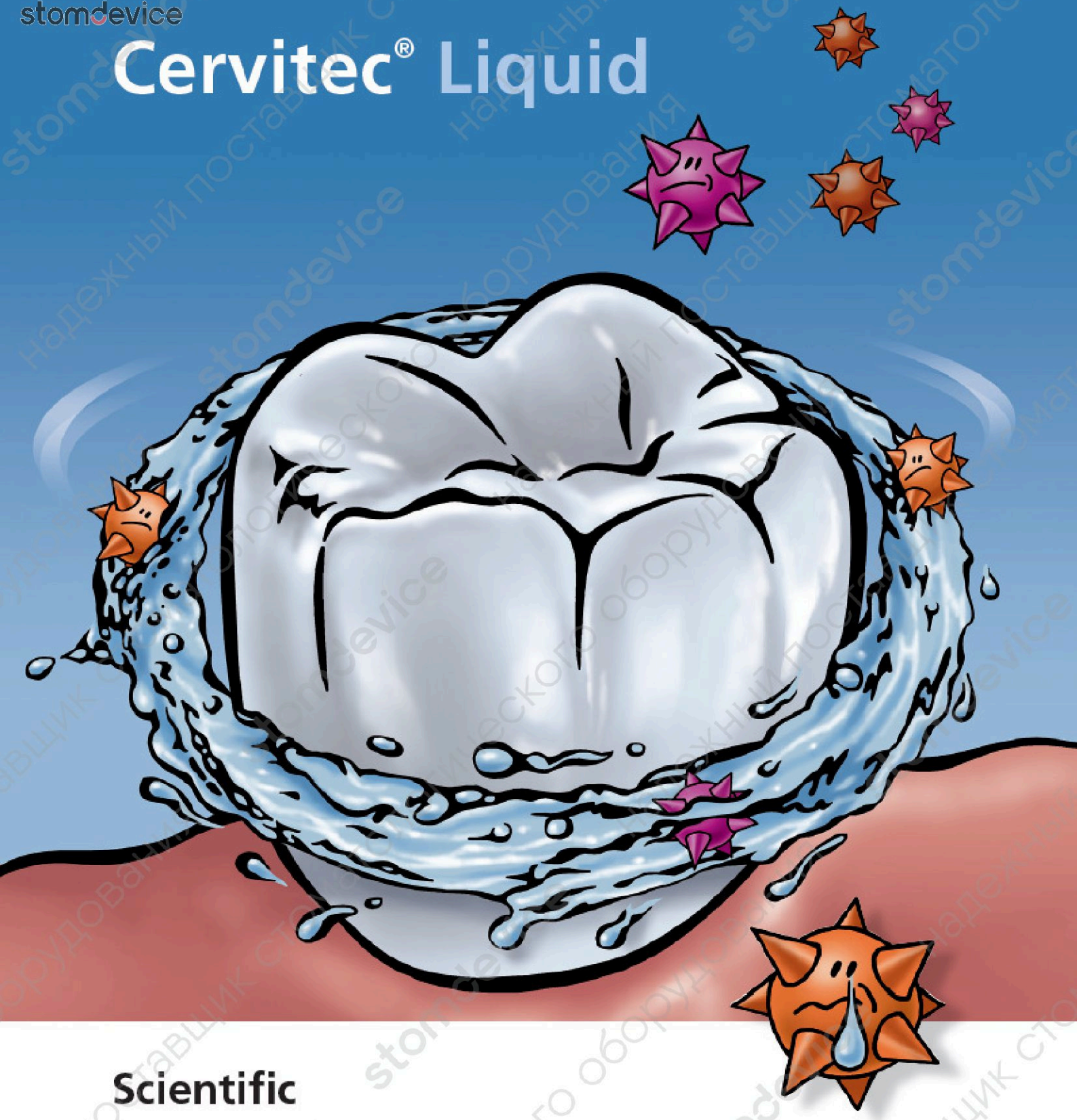
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Cervitec® Liquid



Scientific documentation

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1. Introduction

"Good health begins in the mouth" – this popular saying is not only memorable but also true. Oral health is an important prerequisite for well-being, freedom of pain and social recognition. An epidemiological study conducted in Germany among 2050 volunteers aged between 16 and 79 has revealed a clear connection between oral health and quality of life [1]. Moreover, it has been found that dental pain has an adverse effect on social behaviour [2] and children with a high caries prevalence perceive themselves and are perceived by others more negatively than children with healthy teeth [3; 4].

Poor oral health is often associated with microorganisms living in the oral cavity: bacteria such as mutans streptococci and lactobacilli, or yeast fungi, e.g. candida albicans. Infected dental hard tissues tend to be susceptible to caries, endodontic problems or loss of restoration due to secondary caries, while infected soft tissues may lead to periodontitis, gingivitis and halitosis.

Chlorhexidine (CHX) is the most important antimicrobial ingredient in dental products. This cationic substance adheres to surfaces with a negative charge (e.g. cell walls of bacteria) and thereby inhibits plaque formation and bacterial metabolism. As chlorhexidine deposits on tooth surfaces, it remains available in the oral cavity beyond the time during which the chlorhexidine-containing mouth rinse is applied, ensuring sustained action against harmful oral microorganisms.

Chlorhexidine-containing mouth rinses have been successfully used in clinical applications for many years. Studies have proven the efficacy of chlorhexidine to prevent inflammations of the gingiva as well as plaque accretions [5]. Chlorhexidine has also been found to inhibit the growth of microorganisms, such as *Actinomyces* species, *Candida albicans* and mutans streptococci [6-8] even in susceptible areas around implants [9]. It should be noted that mouth rinses with a content of 0.1% chlorhexidine are as effective in e.g. reducing the formation of plaque as formulations with double the content (0.2%) of chlorhexidine [10]. Another interesting study has shown that the combination of chlorhexidine and xylitol is more effective against oral streptococci than chlorhexidine or xylitol alone [6].

Cervitec Liquid is a ready-to-use, alcohol-free mouth rinse, which is used in undiluted form and effectively inhibits the growth of oral microorganisms due to the combination of chlorhexidine, xylitol and essential oil. Inflammations, periodontal disease, caries and halitosis can therefore be prevented. Furthermore, the antimicrobial effect of CHX mouth rinses such as Cervitec Liquid helps in the treatment of infections and implantological, periodontal and surgical interventions. The Robert Koch Institute recommends the use of antimicrobial mouth rinses for the reduction of the bacterial burden in dental/oral surgical treatments in particular in conjunction with patients that have an increased risk of infection and in all dental surgical interventions involving subsequent saliva-proof wound closure [11]. The American Dental Association ADA also recommends the application of a mouth rinse prior to dental treatment [12]. The antimicrobrial mouth rinse prevents bacteria from entering the patient's body through the wound; invasion by bacteria may cause bacteremia or, in the worst case, endocarditis. In addition, the use of an antimicrobial mouth rinses also protects the dentist and practice team from the formation of bacterially contaminated aerosols [13]. The use of Cervitec Liquid is also indicated for patients with a high caries risk or impaired ability to perform oral hygiene measures.

Arweiler and Sculean [14] list the following indications for the short-term, intensive utilization of CHX mouth rinses:

- Generally before each dental treatment to protect the dental team from aerosol droplets / the oral bacterial flora of the patient
- After surgical interventions
- During intraoral splinting

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- In the case of acute oral diseases (acute, painful gingival inflammations) to compensate for the inability to conduct mechanical oral hygiene measures
- As part of periodontal therapy: to support the mechanical, anti-infective treatment measures in the course of a "full mouth disinfection" procedure

Never mind for which indication they are employed – many CHX-containing mouth rinses entail certain disadvantages: often they taste hot and bitter in the mouth, they leave an unpleasant aftertaste and repeated use may lead to an impaired sense of taste. Because of these drawbacks, the compliance of patients to use these types of mouth rinses on a regular basis is challenged. This may put the outcome of certain treatments at risk. By contrast, Cervitec Liquid offers a pleasant flavour, which motivates patients to use the rinsing solution on a regular basis, enabling them to fight harmful oral micoorganisms successfully.



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2. Composition

Composition of the sales article

Function	Component
Solvent	Water, glycerine, polyethylene glycol, propylene glycol
Tooth-friendly sweetener	Xylitol
Antibacterial ingredient	Chlorhexidine digluconate (0.1 weight %)
Essential oil	Eugenol
Flavouring	Cinnamon flavour (cinnamal), peppermint

pH value	5.5 – 6.2

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3. *In vitro* investigations

3.1 Inhibition zone assay I

Objective: To examine the antimicrobial effect of different mouth rinses on key oral microorganisms

Head of study: Ivoclar Vivadent R&D, Schaan, Liechtenstein

Method: Two percent of the culture solutions (18 to 24 hours old, depending on the strain) of each *S. mutans, L. casei, S. aureus* and *C. albicans* were added to cooled culture medium and 20 ml of the inoculated medium filled into Petri dishes. After the agar had been cooled and solidified, a hole (d=6 mm) was punched at the centre of the agar plate and filled with 50 µl of material. The agar plates were incubated at 37 °C for 24 hours.
The size of the inhibition zone was measured with vernier calipers. After the diameter of the punched hole had been deducted, the radius of the inhibition zone was calculated.

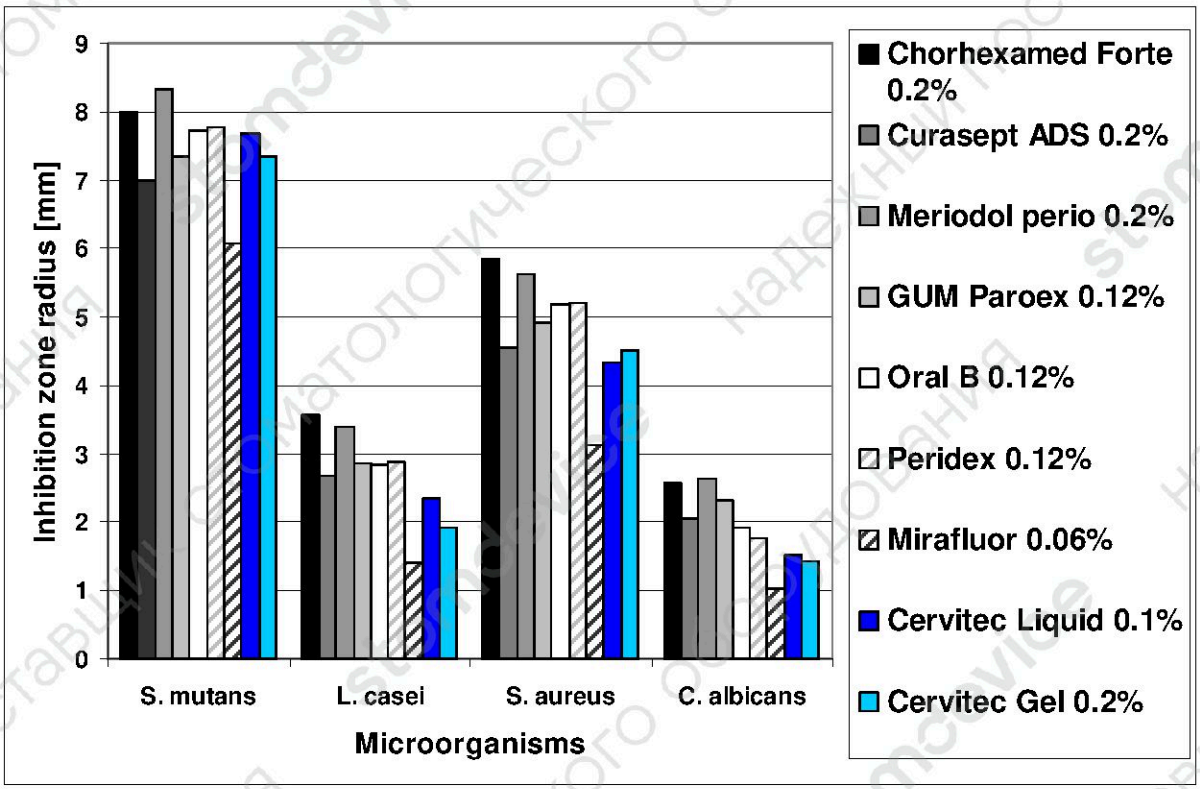


Fig. 1: Antimicrobial effect of various CHX products in an inhibition zone assay. *S. mutans, L. casei, S. aureus* and *C. albicans* were incubated in conjunction with different CHX-containing products. The radius of the inhibition zone was determined after 24 hours.

Results: Mirafluor, which contains only 0.06% of CHX, showed the weakest antibacterial effect. By contrast, the inhibition zone radii of *L. casei, S. aureus* and *C. albicans* were of a similar size in Cervitec as in the other mouth rinses which contain 0.1% CHX. Cervitec Liquid suppressed mutans streptococci, the most important cause of caries, equally well as Chlorhexamed Forte, which contains 0.2% CHX and even better

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than the 0.2-% Curasept ADS mouth rinse. When compared with each other, both Cervitec Gel and Cervitec Liquid show a similar antimicrobial effect against the microorganisms tested (see Figure 1).

3.2 Inhibition zone assay II

Objective: To examine the antimicrobial effect of Listerine (Coolmint and Freshmint) and Cervitec Liquid in conjunction with key oral microorganisms

Head of study: Prof Dr Susanne Kneist, University Hospital Jena, Germany

Method: Bamelli agar was inoculated with 24-hour cultures of the relevant strains and poured into petri dishes. After the agar had solidified, reservoirs were punched (d = 10 mm) and filled with 0.3 ml of the mouth rinses in a standardized fashion. The petri dishes were stored in a fridge for one hour to allow the ingredients to diffuse and, subsequently, the samples were placed in an anaerobic chamber and incubated 35 ± 2 °C for 24 hours. The resulting inhibition zones in the bacterial lawn were measured metrically.

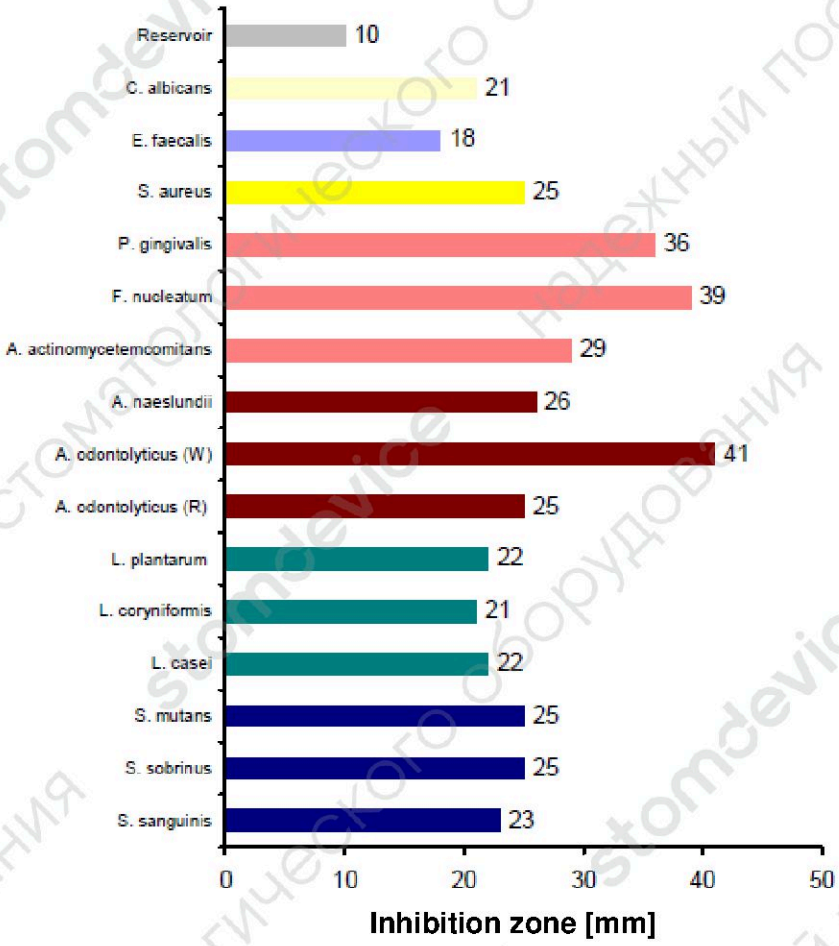


Fig. 2: Inhibition zone size of different oral microorganisms in conjunction with Cervitec Liquid. Cervitec Liquid inhibited the growth of all microorganisms tested.

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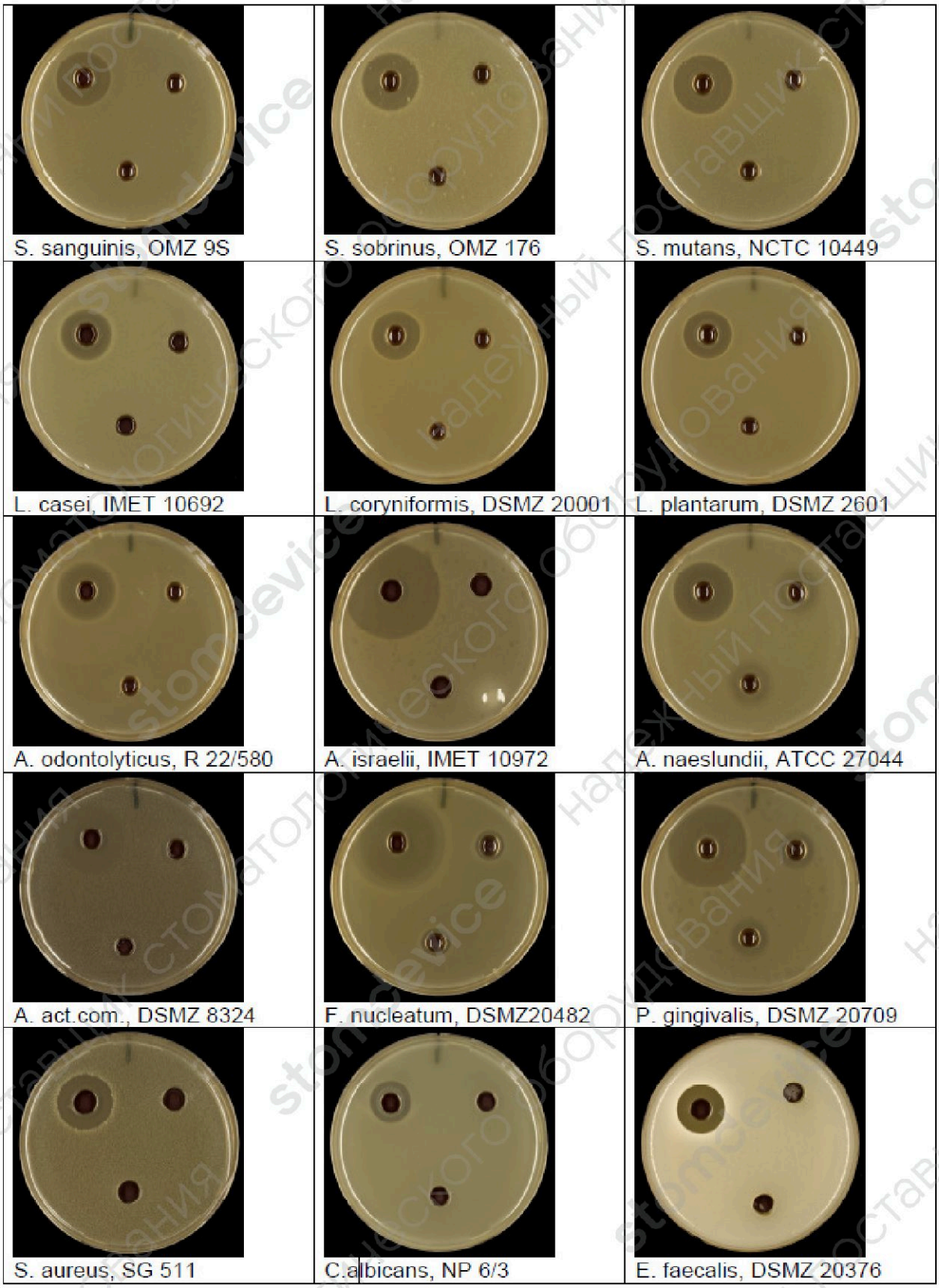


Fig. 3: Inhibition zones in various microorganisms in an inhibition zone assay Reservoir on the top left: Cervitec Liquid; on the top right: Listerine Coolmint, at the bottom: Listerine Freshmint. The larger the uncolonized area around the reservoir, the more powerful is the antibacterial effect of the material tested. In contrast to the two Listerine mouth rinses, Cervitec Liquid inhibited the growth of all microorganisms tested.

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Results: Cervitec Liquid inhibited the growth of all strains (see Figs 2 and 3). The inhibition zones measured up to 41 mm in diameter. By contrast, Listerine Coolmint and Listerine Freshmint only suppressed the growth of *A. naeslundii* (inhibition zone: 18 mm), *F. nucleatum* (inhibition zone: 13 mm) and *P. gingivalis* (inhibition zone: 17 mm). Cervitec Liquid was not only effective against the cariogenic bacteria *S. mutans* and *L. casei*, but also against *Staphylokokkus aureus*. These bacteria are associated with peri-implantitis. Thus, Cervitec Liquid supports in particular implant patients in maintaining good oral health.

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4. *In vivo* investigations

4.1 Effect of Cervitec Liquid on the caries risk level determined with CRT bacteria

Objective: To examine the effect of Cervitec Liquid on the caries risk determined with the CRT bacteria test

Head of study: Ivoclar Vivadent R&D, Schaan, Liechtenstein

Method: Saliva samples were collected from ten volunteers before and after a single application of Cervitec Liquid as well as one, two and six hours after rinsing. The concentration of mutans streptococci and lactobacilli contained in the saliva was analysed using CRT bacteria and the caries risk status of the volunteers before and after rinsing was determined.

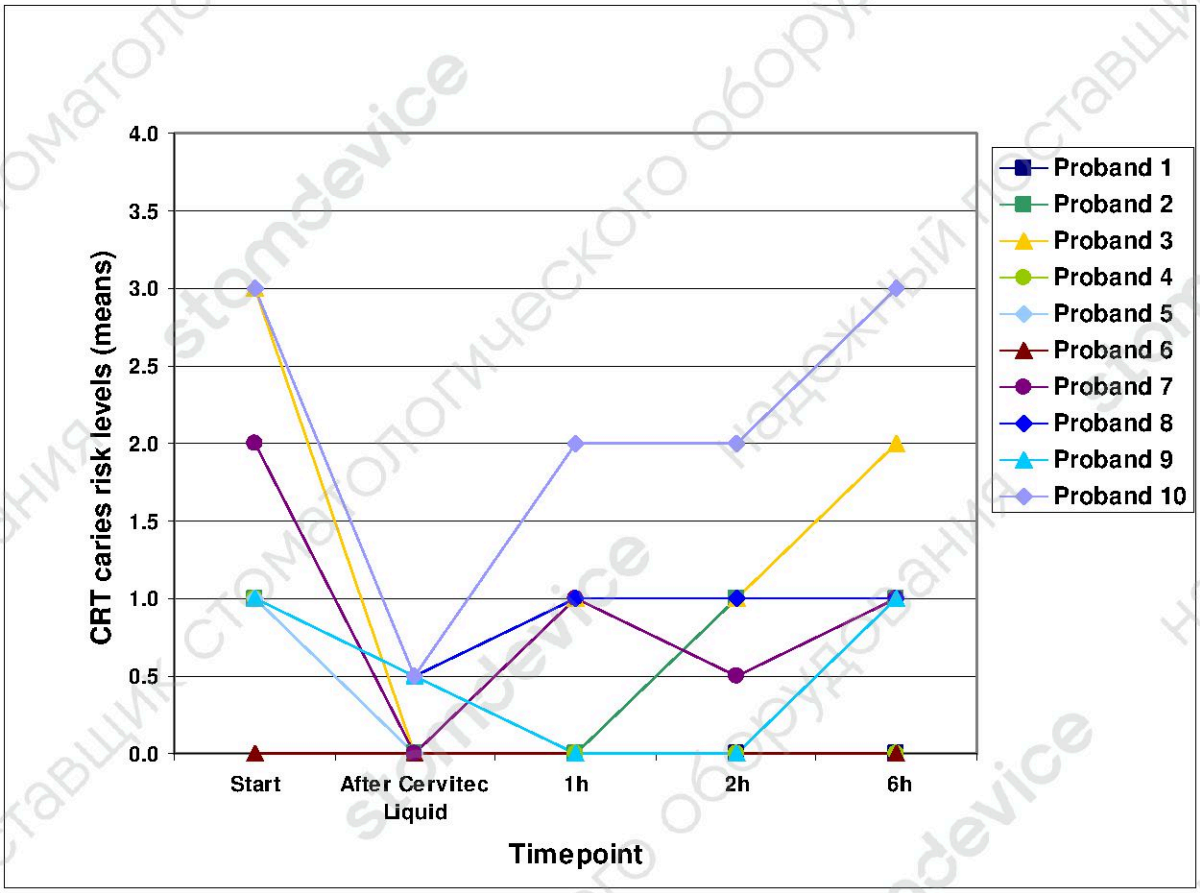


Fig. 4: Caries risk measured with CRT bacteria (*mutans streptococci*) before and after rinsing with Cervitec Liquid. A clear reduction in the caries risk was found immediately after rinsing, as the mutans streptococci count decreased. The mutans streptococci numbers and therefore the caries risk increased again in the hours after rinsing but, however, remained lower than the original value.

Results: The caries risk related to mutans streptococci decreased by up to three levels after the use of Cervitec Liqud (see Figure 4). In most volunteers, the concentration of bacteria in the saliva remained lower for several hours compared to the concentration before rinsing.

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However, no significant reduction in the number of lactobacilli was detected after application of the mouth rinse (see Fig. 5).

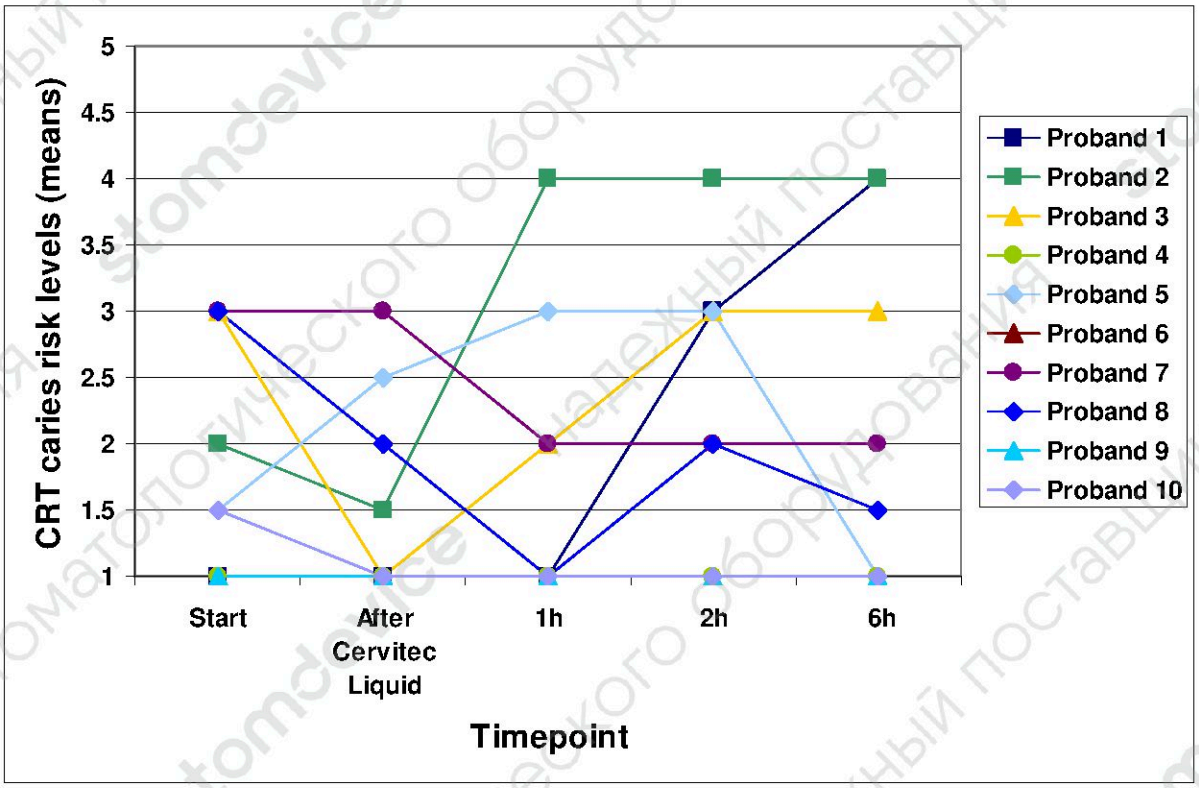


Fig. 5: Caries risk according to CRT bacteria (lactobacilli) before and after rinsing with Cervitec Liquid. No reduction in the number of lactobacilli was detected immediately after rinsing. Later on, the lactobacilli count increased in some patients and decreased in others.

Conclusion: Cervitec Liquid is capable of reducing the caries risk by a (temporary) decrease in the number of mutans streptococci. Consequently, mouth rinses should not be used immediately before a caries risk test is conducted to ensure that a correct result is obtained.

4.2 Bacterial counts in the oral cavity after application of Cervitec Liquid

Objective: To determine the overall bacterial count and the mutans streptococci count in the oral cavity before and after rinsing with Cervitec Liquid

Head of study: Prof Dr Susanne Kneist and PD Dr Dr Wolfgang Bischof, University Hospital Jena

Method: Three volunteers rinsed with water (control group) and another three volunteers with Cervitec Liquid (test group). The bacterial count in saliva was determined immediately after rinsing and after 15, 30 and 60 minutes. Brain heart infusion blood agar was utilized to evaluate the overall bacterial count and CRT bacteria was employed to determine the mutans streptococci count.

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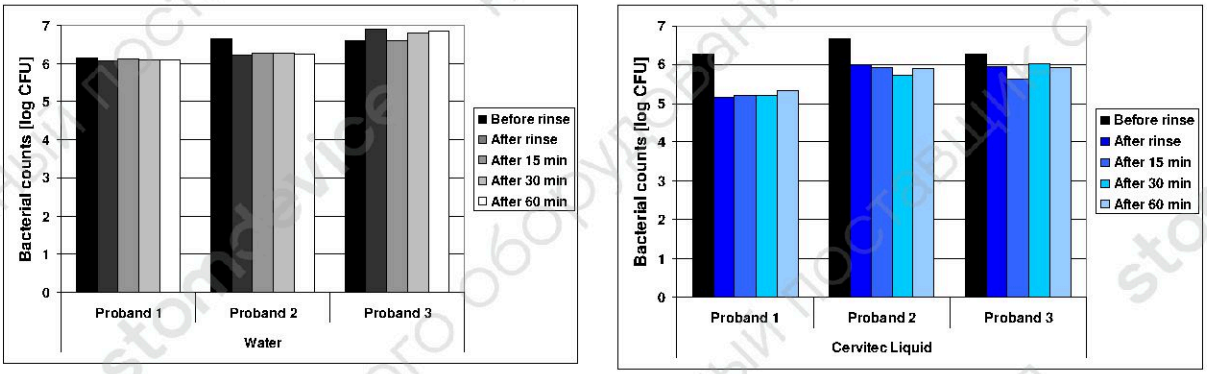


Fig. 6: Overall bacterial counts in the oral cavity before and after rinsing. The volunteers who rinsed with Cervitec Liquid (on the right) showed a reduction in the overall bacterial count cultivated on brain heart infusion blood agar immediately after rinsing until up to one hour later. By contrast, rinsing with water (on the left) did not affect the overall bacterial count.

Results: Rinsing with Cervitec Liquid reduced the overall bacterial count approximately by the power of ten (see Figure 6). This reduction was observed in the volunteers immediately after rinsing and lasted up to one hour. The mutans streptococci counts and therefore the caries risk level according to the CRT bacteria test also clearly decreased (by up to three levels) immediately after rinsing and remained at a low level in the following hour (see Figure 7). In neither of the tests did rinsing with water (control group) result in a clear reduction in the bacterial counts.

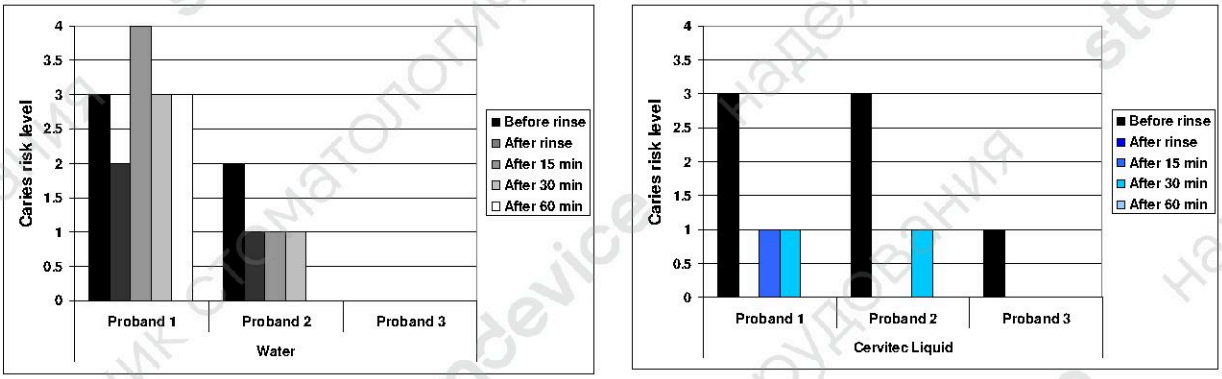


Fig. 7: Caries risk levels according to CRT bacteria (*S. mutans*) before and after rinsing. Rinsing with Cervitec Liquid (on the right) resulted in a clear decrease in the caries risk by up to three levels. Rinsing with water (on the left) only marginally reduced the number of mutans streptococci in saliva.

4.3 Flavour test

Objective: To evaluate and compare the flavour of Cervitec Liquid and other CHX-containing mouth rinses

Head of study: Ivoclar Vivadent Marketing, Schaan, Liechtenstein

Method: Sixty-two volunteers tested in a blinded manner three different mouth rinses (among them Cervitec Liquid) to assess their odour, flavour, feel on the tongue/in the mouth and aftertaste. They then evaluated their

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perceptions on a questionnaire and rated them with marks from 1 (pleasant) to 6 (unpleasant).

Results: Compared with 0.2-% CHX mouth rinses, Cervitec Liquid received better evaluations in all aspectes rated (see Table 1). Compared with other 0.1-% CHX liquids, the feel on the tongue and in the mouth and the aftertaste were rated particularly favourably.

Table 1: Results of the flavour test of chlorhexidine mouth rinses. The table below shows the average marks gained in the evaluations of 20 volunteers. The individual aspects could be rated with marks from 1 to 6, with 1 being the best possible and 6 being the worst possible mark.

Mouth rinse	Odour	Flavour	Feel in the mouth	Feel on the tongue	Aftertaste
Cervitec Liquid 0.1%, Ivoclar Vivadent	2.7	2.5	2.7	2.7	2.9
Chlorhexamed Forte 0.2%, GSK	3.6	4.2	3.8	4.0	4.4
Curasept ADS 0.2%, Curaden	3.6	4.7	3.8	3.3	4.9

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5. Biocompatibility

5.1 Toxicological data

Component	LD_{50}	Species / Application	Source
Glycerine	4.09 g/kg	Mouse, oral	ChemID Plus (1)
Xylitol	15.5 g/kg	Mouse, oral	ChemID Plus (1)
PEG-40 Hydrogenated Castor Oil	5 g/kg	Mouse, intra-ven.	ChemID Plus (1)
Propylen glycol	22 g/kg	Mouse, oral	ChemID Plus (1)
Chlorhexidine digluconate (0.1%)	1.2 g/kg	Mouse, oral	ChemID Plus (1)
Aroma (Optamint)	3.2 g/kg	Rat, oral	HSDB (2)
Cinnamal	2.2 g/kg	Mouse, oral	ChemID Plus (1)
Eugenol	3 g/kg	Mouse, oral	ChemID Plus (1)

5.1.1 Auxiliary materials

The main quantitative ingredients water, glycerine, xylitol, PEG-40 and propylene glycol do not have a relevant acute toxicity (see above table). The LD_{50} values are above 4 g/kg body weight for all the ingredients. Further, xylitol is approved as a food additive without an upper concentration limit (3).

5.1.2 Chlorhexidine digluconate

Chlorhexidine digluconate (CHX-dG) has an LD_{50} value (oral, mouse) of approx. 1.2 g/kg body weight (see Table). The upper limit set by the Cosmetics Directive is 0.3% chlorhexidine (CHX) (free base) for the use as preservative (4). Cervitec Liquid contains 0.06% CHX (free base) and therefore conforms to this directive. The CHX-dG contained in Cervitec Liquid does not pose an increased toxicological risk.

5.1.3 Flavourings

The LD_{50} values of optamint, cinnamal and eugenol range from 2 to 3 g/kg body weight. These ingredients have therefore a low acute toxicity (see Table). Peppermint flavouring (optamint) is approved as food additive in the EU (5). The quantities of Optamint employed in Cervitec Liquid are toxicologically safe. Cinnamal and eugenol are contained in Cervitec Liquid only in minimal amounts (≤ 0.1 weight%) and are therefore toxicologically not relevant. However, cinnamal and eugenol have a certain allergenic potential. Therefore, the Cosmetics Directive requires that these two ingredients are identified on the packaging.

5.2 Conclusion

All components of Cervitec Liquid are approved as cosmetic ingredients in Europe and are employed in Cervitec Liquid within the limits set out for oral products by the Cosmetics Directive.

In view of the data available to date, Cervitec Liquid does not pose an increased toxicological risk to patients or users if it is used for its intended purpose.

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5.3 Literature on biocompatibility

(1) ChemID Plus, http://chem.sis.nlm.nih.gov/chemidplus

(2) Hazardous Substances Data Bank (HSDB): http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

(3) Richtlinie 94/35/EG des Europäischen Parlaments und des Rates vom 30. Juni 1994 über Süßungsmittel, die in Lebensmitteln verwendet werden dürfen

(4) Richtlinie des Rates vom 27. Juli 1976 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten über kosmetische Mittel (76/768/EWG)

(5) EG-Verordnung 1334/2008 Verordnung (EG) Nr. 1334/2008 des Europäischen Parlaments und des Rates vom 16. Dezember 2008 über Aromen und bestimmte Lebensmittelzutaten mit Aromaeigenschaften zur Verwendung in und auf Lebensmitteln

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