This is a certified translation of the German original

BIOSERVICE
SCIENTIFIC LABORATORIES

sarastro GmbH
Dr. Dirk Kreischer
Zum Schacht 7
66287 Göttelborn
Germany

Planegg, 20.07.2009

Bacoban DL 1 %

Dear Mr. Dr. Kreischer,

biocompatibility of your product sarastro®surf.pro-life was tested at BSL BIOSERVICE under project numbers 051691 (acute dermal irritation) and 051692 (LLNA). Under the name of Bacoban, biocompatibility was thus also certified in animal studies. As stated in your communication dated July 14, 2009, you have modified the formulation of your product Bacoban DL 1% as compared to the tested product sarastro® surf.pro-life. The active ingredients in the product Bacoban DL 1 % were reduced for benzalkonium chloride (from 0.71 to 0.26 g), sodium pyrithion (from 0.05 to 0.025 g), a fragrance (from 0.015 to 0,010 g) and polycondensate (from 2.0 to 0.4 g). The components ethanol and isopropanol contained in sarastro® surf.pro-life were replaced by water in the product Bacoban.

In our opinion, a repeat examination of the product Bacoban DL 1 % in animal tests is not necessary. As a bridging study, however, we would recommend to carry out an in vitro test (for cytotoxicity).

In accordance with paragraphs 7 and 8 of the Animal Protection Act, animal tests may only be carried out if absolutely necessary and .... if, despite the exploitation of all usable information resources - the targeted test result is not adequately known or if validation of a well known result by means of a double or repeat test is essential...

With regard to the **animal welfare aspect** and the fact that there is no gain of information, the performance of repeat studies with Bacoban DL 1 % must be opposed from a scientific and ethical point of view.

Yours sincerely,

BSL BIOSERVICE
Scientific Laboratories GmbH

>>Signature<<
Dr. Sandra Schmid
Head of In Vivo Testing
BSL BIOSERVICE Scientific Laboratories GmbH

>>Contact data<<

End of translation

In my capacity of a translator for the English language, duly registered and commissioned by and sworn to the President of the Landgericht (Regional Court) of Augsburg, I do hereby certify the foregoing to be a true and complete translation, whereof the original has been submitted to me. In witness whereof I have hereunder set my hand and seal at Egling, Germany, this 8th day of January 2010.

Ulrike Krosta

Öffentlich bestellte und beeidigte Übersetzerin für die englische Sprache
Ulrike Krosta
Frankenstr. 22
86492 Egling

This is a certified translation of the German original

Sarastro GmbH, Zum Schacht 7, 66287 Göttelborn, Germany

sarastro
future technologies

Your reference	Our reference	Name	Date
	han	Dr. Reiner Hanselmann	December 8, 2009

Bacoban WB:
Biocompatibility and medical assessment of the used chemical substances

Bacoban WB is an area disinfection agent based on water, which is suitable for disinfection of small and large areas. The product is available in a concentrated form (requires dilution). The product is generally applied during a wiping process. Afterwards, Bacoban WB dries without leaving visible traces. But actually a very thin film (< 500 nm) of the product remains on the treated surface after it has dried. In the depth of this film, the solid biocidal components accumulate and diffuse to the surface when the film comes into contact with moisture/liquid. Based on the described procedure it is therefore possible to theoretically derive the risks involved for health. These are as follows:

1. The solution in its concentrated form, the finished solution or the product film come into contact with skin
2. The concentrated solution or the product in the finished solution is swallowed
3. The concentrated solution or the product in the finished solution come into contact with the eyes

Due to its form of application, contact with the skin (epidermis) is the most probable risk. A direct or indirect skin contact may occur during preparation of the concentrate or during application of the finished solution or even when coming into contact with the product after it has dried (e.g. on benches, desks). To minimise the risk for the user, we already made sure during development of the product, that the number of contained biocides was kept at a low level. Despite these measures there are two different risks pertaining to medical compatibility: The risk of the concentrate as well as the finished solution.

Risk posed by the concentrate:

The greatest risk pertaining to medical and biological compatibility derives from the concentrate, because all components are present in a concentrated form. The highest risk is posed by the contained biocides (see individual assessment below).

This is why the concentrated product is marked as caustic and harmful to the environment and certain procedures must be observed when handling the product. Handling the product requires wearing safety gloves for skin protection. The product shall not come into contact with mucous membranes and the eyes. It must not be swallowed and shall be kept out of reach of children, suicidal or mentally-handicapped persons. In case the product comes into contact with the mentioned body areas during handling, rinse the skin, mucous membranes or eyes with copious amounts of water and call for medical attention. If the concentrate is swallowed, immediately see a doctor. As Benzalkonium chloride has tenside properties and the formation of foam after ingestion with water cannot be ruled out, the intake of water after swallowing the product should be avoided. To minimise the risk of direct product contact, Bacoban WB concentrate should only be processed using standard metering devices.

Risk posed by the finished solution:

For the use of Bacoban WB we recommend three types of concentrates: 3 %, 1 %, 0,75 % and 0,25 % solution (*Translator's note: The previous sentence mentions three concentrate forms, but continues by listing 4 different percentages*). The biocides contained in these concentrations are diluted such that Bacoban WB poses no immediate hazard in the sense of the Ordinance on Hazardous Substances.

The statement that the product in its diluted form entails fewer risks is justified with the following arguments: Firstly, from the safety data sheets of the individual biocides it may be gathered that the final concentration as recommended by us only involves a low health hazard (see assessment of individual substances below). Secondly, the alcohol-based product we developed was tested for biocompatibility with otherwise identical biocides. The tests were carried out under GLP conditions by BSL Bioservice Scientific Laboratories GmbH in accordance with DIN EN ISO 10993-1. There was no indication of sensitisation or dermal irritation caused by Bacoban (alcohol-based).

- Certificate dated July 22, 2005, issued by BSL Bioservice Scientific Laboratories GmbH

For Bacoban WB (undiluted) this means that this product presents a lower risk with regard to biocompatibility and side-effects, because the biocide concentration (salts) is the same or lower and two biocides have even been left out in this product (ethanol and isopropanol).

Benzalkonium chloride

Benzalkonium chloride does not evaporate and intake therefore is only possible via direct ingestion or via aerosols. With Bacoban WB this amount will only be small, if it is not swallowed on purpose. Due to its antimicrobial properties, benzalkonium chloride is both used as a component in disinfection agents and e.g. as a preservative in nose drops (Olynth, Pfizer). Therefore it can be assumed that benzalkonium chloride in its undiluted concentration poses no relevant risk when small amounts of the aerosol are inhaled.

Sodium pyrithion

Sodium pyrithion does not evaporate and intake therefore is only possible via direct ingestion or via aerosols. Sodium pyrithion and zinc pyrithion are both used in the field of cosmetics, e.g. in antidandruff shampoos. Both substances have a very similar toxicological profile. Many tests are carried out with zinc pyrithion, therefore, these tests were also considered in this assessment. An extensive literature compilation brought together by the California Environmental Protection Agency in August 2004 provided a survey and assessment regarding a multitude of examinations on chronical exposition to sodium pyrithion. In essence, these documents show that sodium pyrithion only will result in pathophysiologically relevant changes when high doses are administered over a longer period of time.

From a comprehensive compilation and assessment of zinc pyrithion prepared by the SCCNFP on behalf of the European commission derives the recommendation that zinc pyrithion can be used in shampoos and hair-care

products up to a concentration of 1 %. However, it is not recommended to use it as a hygiene rinse for the oral cavity.

The documents allow the conclusion that the amount of sodium pyrithion contained in Bacoban WB (diluted) poses no immediate hazard of inhaling the aerosols. Regarding its sodium pyrithion content, even the ingestion of Bacoban WB is unproblematic, because only a regular intake of one litre of Bacoban WB (diluted) would result in the occurrence of pathophysiologically relevant processes induced by sodium pyrithion.

Literature:

California Environmental Protection Agency: Summary of Toxicology Data of Sodium Pyrithion, August 26, 2004

Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers: Zinc Pyrition, December 17, 2002.

Abbreviations used

SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products

Göttelborn, December 8, 2009

Stamp text:

>>Signature<<

Dr. Rainer Hanselmann

sarastro GmbH
Zum Schacht 7
66287 Quierschied-Göttelborn
Phone: +49(0)6825-800 890
Fax: +49(0)6825-800 891

End of translation

In my capacity of a translator for the English language, duly registered and commissioned by and sworn to the President of the Landgericht (Regional Court) of Augsburg, I do hereby certify the foregoing to be a true and complete translation, whereof the original has been submitted to me. In witness whereof I have hereunder set my hand and seal at Egling, Germany, this 8th day of January 2010.

Ulrike Krosta

Öffentlich bestellte und beeidigte Übersetzerin für die englische Sprache
Ulrike Krosta
Frankenstr. 22
86492 Egling