



Anti-Microbial Emulsions

Regulatory and Efficacy Form

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3 pages

This form is to outline the efficacy of the anti-bacterial agents incorporated into our range of anti-microbial coatings denoted by the coding system "ABWB". Also this outlines the regulatory compliance of the coating ingredients as well as the anti-bacterial additive.

The coating and additive combination are designed to provide invisible protection to the printed surface for the lifetime of the printed work, meaning it can be handled multiple times and microbes of various types will be effectively killed by the protective additive so to avoid passing on to other subsequent handlers of the packaging and reducing transmission of microbes between people.

The active substance silver phosphate glass, has a micron size of less than $\leq 5\mu\text{m}$, and contains a glass carrier which releases silver ions in a controlled manner via an ion exchange mechanism to achieve an antimicrobial effect in products including polymers, coating, paints, sealants and adhesives.

Microbial A-Z

The specialist additives incorporated into our "ABWB" range of waterbased emulsions, have been tested using ISO22196 by BioLab test and proven effective against the following microbes:

Antibiotic resistant Bacteria

- ESBL (producing Escherichia coli) *Found in humans, animals and the environment.*
- CRE Klebsiella *Found in humans, animals and the environment*
- MRSA *Found in the skin, nose and throat of colonised individuals.*
- VRE *Found in human intestines, female genital tract and also the environment.*

Bacteria

- Acinetobacter baumannii *Found in soil and water and passed by people or surfaces.*
- Bacillus subtilis *Found in soil and water, a cause of food spoilage.*
- Campylobacter *Found in raw meat (usuualy poultry), and raw milk.*
- Clostridium difficile *Found in human intestines and passed by people and surfaces.*
- E. Coli & E.Coli O157 *Found in intestines of animals or environments infected with E.Coli containing faeces.*
- Enterobacter aerogenes *Found in soil, water, dairy products and human/animal intestines.*
- Enterococcus faecalis *Found in human intestines, female genital tract and environment.*
- Legionella pneumophila *Found in water i.e. hot tubs, and cooling systems i.e. air con.*
- Listeria monocytogenes *Found in chilled food such as deli meat, smoked salmon, soft cheese and pate.*
- Pseudomonas aeruginosa *Found in soil and water and spread by infections after surgery etc.*
- Salmonella spp. *Found in poultry, pigs, cattle and reptiles also carry this.*
- Shigella spp. *Found in human faeces, pond water, lakes and untreated pools.*
- Staphylococcus aureus *Found in the skin, nose and throat of colonised individuals.*
- Staphylococcus epidermis *Found in the skin, nose and throat of colonised individuals.*
- Streptococcus faecalis *Found in human intestines, female genital tract, and environment.*



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Mould and Fungi

- *Aspergillus niger* Found in soil, as well as indoor and outdoor environments.
- *Candida albicans* Found in the mucoid membranes and on the skin.
- *Penicillium sp.* A common cause of food spoilage by microbial contamination.

Viruses

- Influenza A H1N1 naturally occurring virus in animals and birds

REACH legislation (EU 1907/2006) compliance

The active substances used in our Anti-Microbial range of coatings, are registered under the Biocidal Product Regulation (EU Regulation 528/2012), concerning the making available on the market and use of biocidal products. The active substances contained within our "ABWB" products are, in biocidal applications, considered registered under REACH (Article 15, 1907/2006).

All materials supplied in this range of coatings are compliant with the new SVHC (Substances of Very High Concern), list of REACH (205 substances), which became effective on 16th January 2020.

Biocidal Product Regulation 528/2012 compliance

Within the European Union, biocides are regulated under European Union Regulation (EU) 528/2012; The Biocidal Product Regulation.

Please refer to <http://echa.europa.eu/regulations/biocidal-products-regulation> for further details.

The active ingredients included in our range of Anti-Microbial coatings, are included in the EU BPR review program for inclusion on the BPR's approved list of biocidal active substances. In this review period all active ingredients from the supplier, comply with the BPR's legislative requirements and may be sold, marketed and used in the European Union in accordance with national legislation of Member States. Therefore, our suppliers products and partner products, that are classified as treated articles, do not require national product authorisation.

This statement is applicable for the use of the suppliers additives for the treatment of various manufacturing materials including polymers, wet coatings and other materials used in the production of treated articles.

EU Food Contact Status

a) Coating formulation components

Regulation (EC) No 1935/2004(1) and the Swiss Ordinance 817.023.212(2) require that materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities which could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

All standard coating ingredients incorporated into the formulation of our "ABWB" range of Anti-microbial emulsions are listed in the Swiss Ordinance (817.023.212), Annex 10 or 2, as well as the Plastics Directive Commission Regulation (EU) 10/2011.

Our waterbased emulsion are manufactured in accordance with the CEPE/EuPIA „Good Manufacturing Practices for the Production of Packaging Inks formulated for use on the non-food contact surfaces of food packaging and articles intended to come into contact with food (GMP)".

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None of the substances used are incorporated as “Dual Use Substances” as listed under Directive 2002/72/EC.

b) Active substance food status

The active substance added to these coatings is known as Silver Phosphate Glass and is included in the European Food Safety Authority (EFSA) provisional list of substances and is therefore permitted for current use in food contact applications within specified limits subject to any national authorisation requirements.

Commission regulation (EU) 10/2011: In plastic materials and articles intended to come into contact with food:

Article 6 (5)

“By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.”

In accordance with other silver containing biocides; the silver phosphate glass-based antimicrobial products are subject to a group specific migration limit (SML), of 0.05mg/kg.

The migration of the silver active substance has been tested from treated food packaging as defined in EC Directive 97/48/EC with excellent results. More information on this testing is available on request.

United States (US) Food Contact Status

The silver phosphate glass-based antimicrobial products are permitted for incorporation into a variety of materials (e.g. plastics, coatings, polymeric films, fibres, laminates, adhesives and sealants), with a maximum addition rate of 2.0% w/w. These uses are specified on the products’ US Environment Protection Agency’s approved product label.

Pre market notification to the US Food and Drug Administration (FDA), for these additives as food contact substances has been completed. Details of these notifications can be viewed on the FDA’s database of effective food contact substances.

FDA pre-market notification for the silver phosphate glass antimicrobial product states: *For use only at levels not to exceed 2.0 percent (%) by weight of the finished article, in which the silver content of the finished article shall not exceed 0.038% by weight under Conditions of Use A through H.*

The suppliers silver phosphate glass antimicrobial product states: *For use only at levels not to exceed 1.0% by weight of the finished article, in which the silver content of the finished article shall not exceed 0.022% by weight, under Conditions A through H.*

Any migration of the final article or material remains the responsibility of the party placing the food contact material(s) onto the market.

This should be considered a formal statement from our company.

The information contained in this document is based on our current knowledge and experience up to and including the date of this document.

We will update our customers with any changes where appropriate upon the receipt of any changes to any of these statements in the future at the soonest possibility and we are always open to discussing any particular requirements that may not be covered by this document.

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