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To whom it concerns

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agpure® (including SANPURE® and Xpro™)
Labelling Requirements and Permitted Claims on Treated Articles Background

Dear Sir or Madam,

The requirements for labelling of articles treated with an antimicrobial, biocidal, virucidal product can vary from country to country. RAS markets two effective silver-based antimicrobials, namely

- agpure® W and I series (silver, as a nanomaterial) and
- agpure® ST (silver chloride)

Status:

	EU BPR	US FIFRA/EPA
agpure W and I	Compliant, PT 2, 4 and 9	EPA Reg. No. 83587-3 EPA Reg. No. 85249-1
agpure ST	Compliant, PT 2, 4, 7 and 9	EPA Reg. No. depending on us, please ask RAS

DISCLAIMER: Active healthcare claims on treated articles such as antiviral are not permitted in the USA and require pesticidal device registration. Antiviral claims are permitted in Germany on most treated articles and can be evaluated on a case-by-case basis in other EU territory. Please contact RAS AG for all treated article claims approval prior to commercialization.

European Union

In the European Union treated articles are regulated under the biocidal products regulation (BPR). For articles manufactured in or imported into the EU, the active substance(s) must have been approved or be currently in the ongoing review process under the BPR. In order to comply with BPR Art. 58.3 (a), (b), (c), (d), (e) such treated articles must bear a label with the following information:

a) a statement that the treated article incorporates biocidal products;
    - "This Product is treated with biocidal silver to prevent spoilage by Germs and Microbes"
b) where substantiated, the biocidal property attributed to the treated article;
    - "Germ and Microbe resistant Product" (No primary biocidal function and therefore a treated article)
c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;
    - (e.g. "contains silver")
d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets;
    - • e.g. "contains silver (nano)"
e) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.
    - e.g. "Wash after use at 40°C"

USA

The active substances are registered under the Federal Insect Fungicide and Rodenticide Act (FIFRA) in the US, which enables the marketing of articles treated therewith in the US.

Treated articles for sale in the US may be placed on the market without biocidal labelling requirements provided the active substance(s) has been registered and approved for that specific use, and any claims made on said articles are neither explicit or implied health claims. This condition is referred to as the Treated article exemption, under FIFRA.

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Articles with a health claim must themselves be registered as biocidal products.

RAS AG recommends the following maximal label claim in the US for labelling on a treated article Product:
"*Antimicrobial properties built in to protect the Product*" always to be written together with "*Product does not protect users or others against bacteria, viruses, germs or other disease organisms. Always clean this product thoroughly after each use*."
Both sentences must be printed in type of the same size, style, and colour, and should be given equal prominence. Moreover, such references should not be given any greater prominence than any other described product feature and, importantly the product name itself must not imply a healthcare claim (e.g. Germkiller)

Treated articles (pending)
Companies should be aware it is key consideration to take care with marketing and claims on their treated articles as this can make a distinction between a non-biocidal treated article and a new biocidal product.

ppa. Gregor Schneider
(Head of Business Unit agpure®)