

**Questions reference testing:**

**Q:** What preliminary testing is currently available? Could you please provide us with a list of the testing so we can conduct a data gap analysis to identify additional tests that may need to be performed.

**Q:** Has any product specific testing been conducted on the active and/or the proposed formulation? If so, please provide details and results. Please indicate which studies required in 40 CFR Part 158 Subpart W for a new active ingredient have already been conducted? For any studies, please indicate if they have been conducted in accordance with GLPs as required by EPA.

**Q:** Has any product specific testing been conducted on this formulation? I am trying to determine how much supporting information is existing vs. what needs to be generated.

**A:** Efficacy testing by Covance Lab (contact time 10 minutes, 8 tubes) for *Aspergillus Niger* ATCC® 6275 and *Trichophyton Mentagrophytes* ATCC® 9533

Test Methods for Evaluation of Mildew Remover (MIL-PRF-85570 Specification)

<b>Test</b>	<b>Method</b>
Sandwich Corrosion Test	ASTM F 1110-2
Total Immersion Corrosion Test	ASTM F 483-02
Hydrogen Embrittlement	ASTM F 519-97
Cadmium Corrosion Test	ASTM F 1111-98
Effect on Painted Surfaces	ASTM F 502-02
Effect on Plastics	ASTM F 484-02
Effect on Polyimide Wire	MIL-PRF-85770D
pH Value	ASTM E 70-02
Stress Corrosion on Titanium	ASTM F 945-01
Sealant Adhesions	ADS-61-PRF-2002

**Q:** In Section II Technology Overview, the RfP states that “Any additional data required will be generated by the inventor (self-testing).” Does this mean the inventor will provide us with all required test reports, and that we do not need to find labs to perform any tests?

**Q:** Assuming additional studies are required to complete the 158W data matrix or because they are otherwise necessary to satisfy EPA, will you pay for those directly with the testing laboratories?

**A:** Yes, the inventor will provide all required test reports. The inventor will identify the lab(s), engage and pay for testing as required.

**Question reference Usage:**

**Q:** Is the product used indoors or outdoors? Could you describe more clearly about its usage, especially scope of application.

**A:** The mildew remover product will be used for removal of mildew growth from aircraft interior surfaces.

**Q:** Do the proposed uses involve food contact or possible food contact with residues? Do the proposed uses involve contact with animals?

**Q:** Will the product come into contact with food and/or feed items during usage?

**Q:** Will this be used in or around any food products?

**A:** No, the mildew remover will not come into contact with food/or feed items during the use. There is no proposed contact with animals.

**Questions reference claims and labeling:**

**Q:** Could you please provide the label (and SDS [Safety Data Sheet]) of the AI [Active Ingredient] as well as the EP [Environmental Profile], or at least to provide claims on the label?

**Q:** Please provide a SDS on the active ingredient and formulation if you have prepared them

**Q:** Proposed form and application method for product (e.g. dissolvable powder, dilutable liquid, impregnated carrier) uses, claims and the label you would like to have.

**Q:** Proposed uses / label claims. Why? Data requirement are determine by the proposed product uses. Is the product for food (direct or indirect) vs. non-food, for indoor vs. outdoor use?

**Q:** What are the intended uses?

**A:** The product will be used to remove mildew growth from aircraft interior surfaces which include metals and non-metals such as plastics. The claims will include removal of mildew

growth from metal and non-metal surfaces. The form and application method is a water dissolvable powder to be applied for 10 minutes and flushed with water. No further labeling information has been developed.

The MSDS for Sodium Per-Borate Monohydrate is attached.

**Questions reference ingredients:**

**Q:** Name of the active ingredient

**Q:** Name and CAS [Chemical Abstract Service] number of the active ingredient

**A:** Sodium Per-Borate Monohydrate, CAS number is [10332-33-9](#).

**Q:** Information on the intentionally added inert ingredients. Why? All components in a formulation have [been] cleared for the proposed use in a pesticide formulation. For any inert ingredient that is not cleared, EPA requires that data be provided to demonstrate the toxicity of the material. And EPA charges a service fees to review that data.

**Q:** If this active ingredient is subject to a patent or other intellectual property protection, please provide copies.

**A:** The detailed formulation can be provided under a Non-Disclosure Agreement. There are:

- Active Ingredients (1)
- Corrosion Inhibitors (2)
- Non-ionic Surfactant (1)
- Anionic Surfactant (1)
- Active Ingredient Activator (1)
- Buffer (2)

**Questions reference fees:**

**Q:** Will the company meet EPA's definition of a small business waiver?

**A:** No

**Q:** Will you pay PRIA [Pesticide Registration Improvement Extension Act] fees directly or should those be included in bid?

**Q:** Will you pay the testing fees directly or will [the contractor] be required to pay the fees? If we will be required to pay the testing fees, can we put a cap on these fees?

**A:** Yes, the inventor will pay the testing fees directly to the testing facilities.

**Questions reference manufacturing:**

**Q:** Does the proposed manufacturing site have an EPA establishment number. If not, is obtaining that part of the project?

**Q:** What level of information/support will you provide, [e.g.] will you provide all information on product chemistry, manufacturing method, storage stability etc. for EPA application?

**A:** The intent is to license the Intellectual Property to a manufacturer in a competitive/negotiated process. The product chemistry can be provided under a Non-Disclosure Agreement. The inventor will provide all required tests for EPA application, such as storage stability.

**Other Questions:**

**Q:** If you have had any discussions or correspondence about this project with the EPA OPP Antimicrobials Division, please provide any documents and a description of any discussions.

**A:** Only general discussions have occurred with an EPA Ombudsman reference process.

**Q:** Please explain why you believe this product will contain a new active ingredient

**A:** Sodium Perborate Monohydrate was used for detergent formulation not as pesticide ingredient.