



AMGUARD Environmental Technologies Fact Sheet – Naled Registration Review DIBROM® Concentrate and TRUMPET® EC

July 20, 2021

What is the relationship between AMGUARD Environmental Technologies and AMVAC?

The Environmental Products division of AMVAC Chemical Corporation recently rebranded as AMGUARD Environmental Technologies. To read the full announcement, please visit www.amvac.com/rebrand.

Why are DIBROM® Concentrate and TRUMPET® EC undergoing review, and what is the RED?

All insecticides are required by the pesticide statutes FIFRA and FQPA to be evaluated every 15 years. Reregistration is not specific to Naled and is part of the normal regulatory process that all pesticide products are required to follow. This US EPA periodic review is designed to consider the best available methods and ensure that previously registered pesticides can still be used safely without unreasonable risks to the public or environment.

The last Reregistration Eligibility Decisions (RED) for Naled, the active ingredient in DIBROM® Concentrate and TRUMPET® EC, was issued in July 2006 with certain mitigation measures including handler protection. This [Registration Review](#) process must be completed by October 2022 and involves 6 phases. Currently, the US EPA is working on phase 5 for Naled; the Proposed Interim Decision (PID). The Naled PID is scheduled for September 2021, possibly sooner.

How long does Registration Review take to complete?

This varies for each public health insecticide and depends upon the extent and the complexity of the risk assessments. The Registration Review cycle for Naled began in March 2009 (i.e., Preliminary Work Plan posted to docket) and the final 'Interim Decision' is expected to be issued by October 2022.

Is AMGUARD supporting Naled throughout the Registration Review process?

Yes, AMGUARD has committed considerable resources and continues to work with the EPA and other stakeholders in full support of EPA's re-evaluation programs, which includes but is not limited to the study of environmental fate, ecological effects, toxicology, food safety, and potential human exposure issues.

Should I change the way in which I use/handle Naled during Registration Review?

No, the six-phase review process is lengthy and culminates with regulatory decisions that might require modifications to how a product is used, but until this review process is finalized the label on the product container describes all approved directions for the safe use and handling of the product.

Will Registration Review impact my ability to use Naled?

During the Registration Review process, Naled products can continue to be used in accordance with approved labeling found on product containers. While we do not anticipate significant changes to Naled labeling with the completion of the review process (i.e., publication of EPA's Interim Decision), EPA might require mitigation measures that would be implemented over a defined period.

Does using Naled during Registration Review increase my liability in any way?

No. The current label is still the law.



Who is involved in the overall process?

EPA, as the regulatory authority that evaluates all registered uses of Naled. All parties are invited to comment on each of EPA's assessments during the Registration Review process: AMGUARD Environmental Technologies, as the registrant that develops data in support of the continued registration of Naled products; public health professionals as applicators of Naled products; the general public as those who mosquito control is provided to protect.

If label changes are proposed when Registration Review is complete, what happens to my inventory?

Depending on the decision of the EPA there may be no changes to the current EPA approved label and therefore stakeholder inventory is not impacted in any way. In the event of required label changes, there is a designated grace period (typically 18 months) which allows existing inventory to be used and move through the channels of trade.

Will AMGUARD continue to produce Naled throughout the Registration Review period?

Yes, manufacturing, distribution, sales, customer service, technical support and drum recycling programs will all remain intact throughout the process and beyond. Also, the latest information can continue to be found at www.amvac.com and www.mosquitocontrolfacts.com.

Where will EPA decisions and any potential label changes for Naled be posted?

When the [EPA PID](#) is posted, everyone will have the opportunity to review and comment on any proposed label changes. EPA must consider all comments before posting their final 'Interim Decision'. If changes are required, then AMGUARD must submit to EPA revised labeling for approval within a specified period. Once EPA approves the label changes, there will be a designated period (typically 18 months) after which product entering the channels of trade must bear the new revised labeling.

Will the reregistration impact the price I pay for Naled?

Pricing is a function of many variables. Registration Review does not directly impact pricing as the process is recurring and budgeted in the cost of manufacturing. Naled, including DIBROM[®] Concentrate and TRUMPET[®] EC, are manufactured solely in the USA, in relatively small quantities, to serve a relatively small market. As a result, the pricing of such specialized formulations is more likely to be impacted by volume, or a reduction thereof. Your continued support and use of these unique formulations will help ensure continued control of mosquitoes, and the best overall value.

Will other products that I use be going through Registration Review?

Yes, all chemicals registered as of October 2007 undergo Registration Review. Registration Review is not specific to Naled and is part of the normal regulatory process that all pesticide products are required to follow.

What can I do to support products that I use when undergoing EPA Registration Review?

Keep EPA informed on the public health significance of use practices and the value of registrations for the key products in your operations. Stakeholders should participate in the Registration Review process by [providing comments](#) on EPA's proposed decisions. EPA will consider all comments in its risk-benefit analysis. Those comments on the importance and value of Naled products are key to EPA's understanding the significant role these products play in the control of pestiferous and vector mosquito species during normal operations and public health emergencies.