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Foray[®]

VALENT BIOSCIENCES.

Some commonly asked questions on the use of Foray:

1. What is Foray?

Foray is microbial or biorational insecticide. It contains the spores and unique crystalline proteins produced by a naturally occurring bacterium, *Bacillus thuringiensis*, subspecies *kurstaki* (*Btk*). These biological components are combined with approved ingredients and water to make the final product.

2. How does Foray work?

Foray must be eaten by the target pest larvae in order to cause mortality. The ingested bacterium is not what kills the larvae, but rather a protein crystal produced by the bacterium. The crystal carries a toxin that is lethal to some lepidopteran larvae. To release the toxin, the crystals require the alkaline environment found in the gut of lepidopteran larvae. When Foray is eaten by a susceptible larva, the toxin is released, the midgut wall is destroyed, the gut becomes paralyzed and the larva stops feeding within a few minutes. Destruction of the midgut wall allows the bacteria to enter the blood of the target insect, causing full-scale infection and death of the insect. This process may take 3-5 days so, unlike the situation with some chemical insecticides, there is not an immediate knockdown of insects following treatment.

3. How is Foray different from chemical insecticides?

Btk is not a chemical. Chemical pesticides kill a wider range of insects, including many beneficial ones. The active ingredient of Foray is a natural bacterium, *Bacillus thuringiensis*. It has been shown to kill certain caterpillars such as the destructive gypsy moth. Additionally, Foray is quickly biodegraded in nature, unlike a number of chemical pesticides that form by-products and residues of environmental concern.

4. Why is *Btk* used for forest spraying?

Btk was developed in response to the growing concern among the scientific community and the public in the 1960s and 1970s over the use of chemical pesticides in the forest environment. At that time, forest managers realized that an alternative to broad spectrum chemical insecticides would be needed if forest protection was to remain a component of future forest management efforts. The new insecticide would have to be effective when applied in small amounts, more host-specific than chemicals, more quickly broken down in the environment than chemicals and harmless to non-target organisms such as bees, birds, fish and mammals. As well, the cost of the new insecticide would have to be comparable to the cost of chemicals.



Btk was not an immediate success in terms of effectiveness and cost, but intensive research and development produced a product that now meets all of these criteria. *Btk* is now the material of choice in the majority of forest protection programs in North America. This product has gained a level of public acceptance that was unheard of even 10 years ago and, as a result, *Btk* is widely used to protect trees from insect infestations in both rural and urban settings. The major reason that *Btk* is used today is because it is considered ecologically friendly and effective.

5. How effective is Foray?

Foray's effectiveness is comparable to chemical applications in controlling many pest insects when pest population densities are low to moderate. Foray is less likely to be as effective as chemicals when pest populations are extremely high unless multiple applications are conducted. However, a control strategy does not have to kill all the target insects in order to be successful. In fact, studies indicate that there are benefits to maintaining some pest insects in an area to support the population of natural enemies.

Because it can take several days for Foray to kill larvae, there is not an immediate reduction in the pest population as is the case when some chemical insecticides are used. This has created the erroneous perception that Foray does not work. Foray does work, but it takes a little longer to see the results.

Appropriate conditions are essential for Foray to be effective. Foray is sensitive to sunlight and heat and will only persist on foliage for 3-7 days. Since Foray has to be eaten to kill target insects, sprays are most successful when medium-sized caterpillars are actively feeding.

Depending on the life cycle of the pest and climatic conditions, more than one application of Foray may be necessary to achieve the desired level of control. When eradication is the goal of a control program, a single application of Foray may be somewhat less effective than some chemical insecticides in reducing the population to zero. However, because of its low impact on non-target organisms, Foray is the product of choice for most forest pest control programs (including eradications) conducted in North America and around the world.

6. Is Foray harmful to humans and animals?

As required by the United States Environmental Protection Agency and Health and Welfare Canada, extensive oral and intravenous animal studies have been conducted with no evidence of any poisonous, infectious or disease-causing effects found. In inhalation tests with *Btk*, there were no mortalities and the *Btk* was shown to have a low pathogenic potential.

Feeding, skin, breathing and eye irritation animal studies were also carried out with Foray. No toxic effects were seen when significant quantities of Foray were fed or inhaled. Very mild, temporary skin irritation and moderate, temporary eye irritation were observed in the tests when Foray was applied directly to the skin and into the eyes. These effects were totally reversible.

In addition, the Environmental Protection Agency and Agriculture Canada have determined that Foray is exempt from the requirement of tolerance on all labeled crops. Due to this exemption, there is no required interval before re-entering a sprayed area. This exemption is based on extensive testing of *Btk* to determine both short-term and long-term effects on humans and warm-blooded animals.

Finally, *Btk* has been used extensively in commercial urban and rural forest pest management for over 30 years. A solid record of safety and health has been amassed over this time.



7. What effect will *Bt* have on people – especially those with immunodeficiency, asthma or allergies? *Bt* is a common bacterium found in soils throughout the world. People are exposed to *Bt* and many other microbes every day. Many of the microbes we encounter, including *Btk*, do not produce any toxins which affect humans.

Btk and other common microbes are frequently found in blood, urine and other samples from healthy people. It has been shown that the presence of *Btk* in patient specimen samples is not indicative of pathological or toxic effects. As with many other microbes naturally present in the environment, it can be detected as an insignificant contaminating organism among infection-causing organisms isolated from patient samples.

Individuals with an immunodeficient condition are somewhat more likely to be affected by microbes that are normally controlled by a healthy immune system. Such microbes are referred to as opportunistic pathogens. *Bt* is not considered an opportunistic pathogen.

Exposure to a *Btk* spray program is not likely to result in the development of new allergies, asthma or other hypersensitive reactions.

Individuals with pre-existing allergies, asthma or hypersensitive individuals, especially those sensitive to normal exposure to soil or smoke and pollutants, could feel some temporary effect.

The exposure level to *Btk* from an aerial spray program is very low in comparison to the levels applied in safety and health-related testing. Even at higher levels used in tests, *Btk* has been shown to be safe. That safety has been confirmed in over 30 years of use in urban and rural applications.

Individuals with any of the particular medical conditions described above should consider seeking the advice of their physician.

8. Besides *Btk*, what other ingredients are in Foray? Will they harm the environment?

Foray is a biological insecticide which contains spores and crystal-shaped proteins produced by the naturally occurring bacterium *Bacillus thuringiensis*, variety *kurstaki*, or *Btk*. Foray is a very selective insecticide and is not designed to control a wide variety of insect species.

All *Bt* products, including Foray, are produced in a similar fashion. The *Btk* is grown in large enclosed fermentation tanks. Foray is produced using ingredients and technologies which are similar to those used to make beer or spirits. During fermentation, the bacteria (*Btk*) reproduce in a pre-sterilized growth medium containing basic food sources, such as corn, potatoes, grains, etc. After the fermentation is complete and the bacteria are grown, the fermentation material, including the *Btk*, is collected. This material becomes the basic ingredient of Foray.

This basic ingredient is composed of the *Btk*, which is the active ingredient, and the residual fermentation growth material and water. The water and residual fermentation growth material are referred to as "inerts" or inactive, because they are not "active" against insects. Several other inerts are added to this fermentation material, *Btk* and water, to make up the final formulations of Foray. These other ingredients comprise a small proportion of the total formulation.



The other inactive or inert ingredients are added to maintain the quality of the *Btk* formulation, to make it easier to handle and to protect the activity of the *Btk*. Some of these ingredients help ensure the microbial quality of Foray by acting to control the level of possible contaminating natural microorganisms. These ingredients, added in very minor amounts to control contaminating bacteria and molds, are also used in many foods in Canada and the U.S. for the same purpose.

Additionally, and of considerable importance, not just the *Btk* powder itself, but our final end-use formulations are tested toxicologically. In this process the safety of both the active ingredient and inerts is assessed and quantified.

9. How can we prove Foray is not a harmful product?

We can never prove that a product is absolutely safe. We can only demonstrate that when Foray is applied following the label instructions, that the risk to non-target organisms, whether they are birds or humans, is acceptably low. There are many drugs on the market today that, when properly taken, will effectively relieve pain or even save lives. Those same drugs come with the warning that if used improperly, they can be harmful or even cause death. As a society we must set standards, and we do not permit the sale of commercial products until they have met those standards. Foray does meet the safety standards set in the USA, Canada and in all other countries. It is also acknowledged that Canada has some of the toughest regulatory standards in the world.

In the United States and Canada, commercially available products are reviewed and certified for use by federal agencies, including the Environmental Protection Agency in the United States, and in Canada, several agencies including the Pesticide Management Regulatory Agency (Health Canada), Agriculture Canada, Natural Resource Canada, and Environment Canada. All pesticide applications must comply with local, state/provincial and federal regulations. In addition, researchers continue to monitor programs for potential impacts.

10. Will spraying Foray damage other plants?

Foray has been sprayed on millions of acres of trees and other plants. There have been no reports of any plant damage. Foray and other *Bt* products produced by Valent BioSciences are commonly used on market gardens and in greenhouses.