

Finalyse[®]: A Novel Pre-harvest Hide Wash

OVERVIEW

- Novel pre-harvest hide wash used to reduce *E. coli* O157:H7 and other Shiga toxin-producing *E. coli* (STEC) pathogens in beef cattle
- Highly effective in reducing *E. coli* O157:H7 at the plant
- Contains naturally occurring phages developed specifically to reduce *E. coli* O157:H7 and other STEC pathogens
- Safe to workers, equipment and environment
- Key step in a multi-hurdle food safety intervention program
- One-liter bottle treats 3,000 head of cattle

MODE OF ACTION

Finalyse[®] contains a mixture of naturally occurring phages with a unique mode of action that specifically targets *E. coli* pathogens.

- Phages in Finalyse use *E. coli* as host cells to rapidly replicate¹
 - Phage replication weakens the *E. coli* cell wall, which bursts and releases new phages to destroy additional bacteria within 30-40 minutes²
- Phage attachment compromises an *E. coli* cell within 5 minutes²
- Finalyse dwell time is equal to time required for phage to find host cell. A one-hour dwell time equals adequate incubation time for $\geq 1_{\text{Log}}$ reduction³

EFFICACY

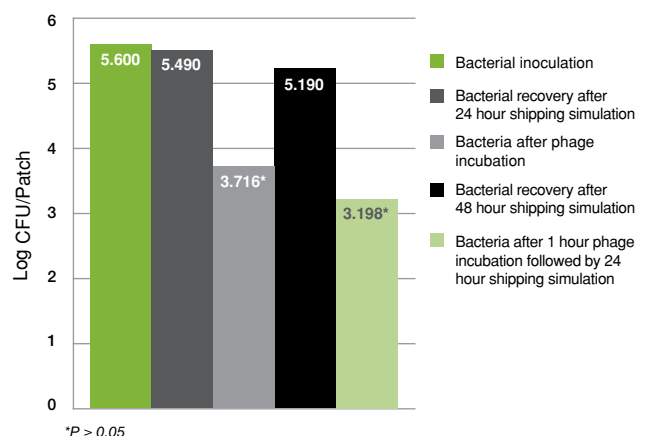
Trials in-lab, in-plant and in simulated commercial settings demonstrate Finalyse efficacy.

Surrogate Model Studies²⁻⁴

- A bacterial culture of a non-virulent *E. coli* surrogate was grown, diluted and the cell suspension was applied to hide patches to simulate cattle application

- After attachment period, Finalyse and control water washes were applied to hide patches with a one-hour dwell time
 - Effectively reduced *E. coli* O157:H7 by $\geq 1_{\text{Log}}$ after one-hour phage incubation
 - Generated a 1 to 2_{Log} reduction of *E. coli* O157:H7 compared to tap water control
 - Efficacy was maintained as bacterial levels increased

Hide Patch Results 10⁸ PFU with 10⁵ Surrogate Log CFU/Patch

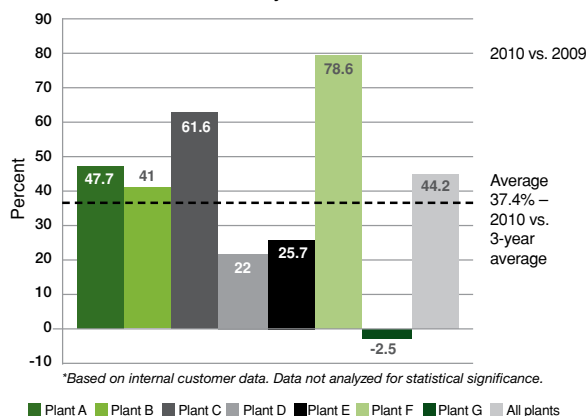


- More effective ($\geq 2_{\text{Log}}$ reduction) at room temperature (24°C) but maintains a $\geq 1_{\text{Log}}$ reduction at temperatures of 38°C
- Further validation testing verified that *E. coli* O157:H7 host cells are immediately unviable upon Finalyse phage injection

Prevalence of *E. coli* on Variety Meats^{5*}

- Conducted at seven commercial facilities; Finalyse-treated cattle compared to same time period previous year and over 3-year average
- Finalyse reduced *E. coli* prevalence by 44% compared to previous year
- Finalyse reduced *E. coli* prevalence by 37.4% compared to 3-year average

Prevalence of *E. coli* on Variety Meats^{5*}



The Passport Food Safety Solutions team will coordinate with plant personnel to help:

- Identify the best system location
- Confirm space and utility requirements
- Install the service system
- Calibrate and regularly validate titers
- Train plant personnel

NOVEL APPLICATION SYSTEM

When used according to label directions, Finalyse and the Finalyse Application System™ easily configure to current pre-harvest, hide-on spaces.

- Applied as an overhead spray system in the holding pens or lairage area spray system
- Can be added to multiple pre-harvest, hide-on application points both inside and outside the plant

SAFETY¹

The Finalyse solution uses naturally occurring phages to destroy harmful bacteria in a natural and safe process.

- Phages are found in soil and water and will naturally degrade without a host
- Phages are safely used in a variety of agricultural and food-safety applications because of their attraction to very specific hosts



For questions or to learn more about the Passport Food Safety Solutions product portfolio, call 515-334-8035 or visit www.passportfoodsafety.com.

The label contains complete use information, including cautions and warnings. Always read, understand and follow the label and use directions.

The sales and delivery of Passport Food Safety Solutions food safety products will be expressly governed by and subject to the limited product warranty and other terms and conditions of sale available at www.PassportFoodSafety.com.

¹Information adapted from the OmniLytics website at http://omnilytics.com/home_info/home_info_technology.html.

²Hyde, J. "Optimization and validation of phage treated non-pathogenic *E. coli* in the beef hide patch model." Data on file.

³Pillai, S., C. Rambo, and J. McReynolds 2013. "Finalyse Surrogate Research Model." Data on file.

⁴Bose, S.K. and R.J. Warren. 1969. "Bacteriophage-induced inhibition of host functions II. Evidence for multiple, sequential bacteriophage-induced deoxyribonucleases responsible for degradation of cellular deoxyribonucleic acid." *J. Virol.* 3:549-556.

⁵Weekly VM-EC 7% Update 2007- 2010 ytd. 2012. Data on file.

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