United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-04-002 September 2003

# Lactofen TRED Facts



EPA has approved the "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Lactofen." The Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by FQPA in 1996, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of enactment of FQPA. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or the tolerances are revoked.

The Agency's TRED for lactofen includes a review of dietary exposure to lactofen from food and drinking water. Lactofen was initially registered after 1984, and it meets the Agency's current health and safety standards for agricultural workers and risks to nontarget organisms. Therefore, the TRED does not address these risks. The TRED indicates that lactofen, by itself, poses no risk concerns within the limits of the existing tolerances; therefore, no risk mitigation is needed, and no further actions are warranted at this time. The two (2) tolerances for lactofen in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of the FFDCA. This fact sheet summarizes the information contained in the TRED and related documents for lactofen.

**Uses**

- Lactofen is registered for use as an herbicide on snap beans, soybeans, cotton, kenaf, and forestry (non-food use) for both pre- and post-emergent control of broad leaf weeds. Lactofen is not registered for residential use. Although not currently registered, the proposed new food uses of lactofen on peanuts and cotton were included in the risk assessment to support the establishment of new tolerances for these two crops.

- Lactofen is sold in the United States under the trade names Cobra® and Stellar®. Lactofen is formulated as technical, manufacturing use product, and emulsifiable concentrate.

- Lactofen may be applied by aerial and ground application; band treatment, broadcast, directed spray, low volume spray, soil broadcast treatment, and soil incorporation. It is generally applied at a rate of 1 lb active ingredient (ai) per acre (A) or less per application. No more than 1 lb ai/A lactofen may be applied to a site in a single year.

- Approximately 235,000 pounds of lactofen ai are applied annually to nearly 2.2 million acres. Lactofen's largest markets in terms of total pounds of ai applied annually are soybeans (85%) and cotton (12%). The remaining use is primarily on fresh beans.

**Health Effects**

- Lactofen has low acute toxicity via the oral, dermal, and inhalation routes of exposure; causes mild skin irritation; and is not a dermal sensitizer. The manufacturing use product is a moderate eye irritant.

- EPA recently revised the cancer classification of lactofen based on new toxicity studies and the Agency's 1999 Cancer Risk Assessment Guidelines. Lactofen is now considered to be a threshold carcinogen, which means that lactofen is unlikely to be carcinogenic at low doses and is carcinogenic only at high doses. See the lactofen Overview document for details.

**Human Health Risks**

**Dietary (Food and Drinking Water)**

People may be exposed to residues of lactofen through food or drinking water. EPA has assessed the dietary risk posed by lactofen and found that acute and chronic dietary risk from food and drinking water are below the Agency's level of concern. In addition, dietary cancer risk estimates are also below EPA's level of concern.

People may also be exposed to acifluorfen, a degradate of lactofen, in drinking water. Because acifluorfen is also a degradate of sodium acifluorfen, another herbicide registered for use in agricultural and residential settings, EPA included acifluorfen derived from both lactofen and sodium acifluorfen in the drinking water assessment. The Agency does not have a concern for drinking water exposure to the acifluorfen degradate from all sources.

**Residential Risks**

Lactofen is not registered for use in residential settings; therefore, a residential risk assessment was not necessary.

**Aggregate Risk**

Aggregate risk considers the combined exposure to pesticides through food, drinking water, and, if appropriate, residential uses. Because there are no residential uses of lactofen, there is no residential exposure to consider in the aggregate risk assessment; therefore the aggregate assessment for lactofen includes exposures only from food and drinking water. The aggregate risk from lactofen is not of concern.

Because lactofen degrades to acifluorfen in the environment, EPA also conducted an aggregate risk assessment for the acifluorfen degradate from all sources. To do this, the Agency considered the risk from combined exposures to the acifluorfen degradate from food and water from use of both lactofen and sodium acifluorfen and exposure from the residential use of sodium acifluorfen. EPA does not have a risk concern for aggregate risk from the acifluorfen degradate derived from all possible sources.

**Tolerance Reassessment Decisions**

Tolerances for lactofen in or on raw agricultural commodities for plants are currently established for the combined residues of lactofen and its associated metabolites, but will be revised to include only lactofen parent. The two existing tolerances for lactofen have been reassessed and will be lowered from 0.05 ppm to 0.01 ppm. There are currently no tolerances for lactofen in processed commodities or animal commodities, and the available residue data indicate that tolerances for these commodities are not necessary. No maximum residue limits (MRLs) for lactofen have been established or proposed by Codex; therefore, there are no issues with the compatibility of U.S. tolerances with international MRLs.

**Risk Mitigation/Data Needs**

Because no risks have been identified from exposure to lactofen or its acifluorfen degradate, no risk mitigation is necessary at this time. However, the following confirmatory data requirements have been identified for lactofen:

- Prenatal Developmental Toxicity Study in Rabbits (OPPTS Guideline 870.3700, current data gap, two developmental toxicity studies are required for every food use chemical)

- Confined Rotational Crop Study (OPPTS Guideline 860.1850, required because confined rotational crop study in root crops indicated minimal uptake of radioactivity in carrots and radishes planted in a field treated the previous season with lactofen).

**Next Steps**

- A Notice of Availability of this tolerance reassessment decision document for lactofen will be published in the *Federal Register* in January 2004. A copy of the 2003 TRED

and supporting documents are available on the Agency's website at www.epa.gov.edockets and www.epa.gov/pesticides/lactofen.htm.

- A Data-Call In (DCI) will be issued for the confirmatory data requirements identified above.