

greater than 5 gram/kilogram (g/kg) body weight and the acute dermal LD<sub>50</sub> is greater than 2 g/kg body weight. Concentrations of less than 30% alkyl (C<sub>12-14</sub>) polyglycosides are non-irritating to skin. Alkyl (C<sub>12-14</sub>) polyglycosides are not dermal sensitizers.

2. *Genotoxicity*. Based on studies conducted with alkyl (C<sub>12-14</sub>) polyglycosides, alkyl (C<sub>10-16</sub>) polyglycosides are considered non-mutagenic. In the bacterial gene mutation study (Ames test), alkyl (C<sub>12-14</sub>) polyglycosides did not cause an increase in revertants, compared to controls, with or without metabolic activation. In the *in-vitro* cytogenetic study, alkyl (C<sub>12-14</sub>) polyglycosides did not cause an increase in chromosomal aberrations, compared to controls, with or without metabolic activation.

3. *Reproductive and developmental toxicity*. In a developmental toxicity study, test animals were treated with alkyl (C<sub>12-14</sub>) polyglycosides, by gavage, on days 6 through 15 of gestation at doses of 0, 100, 300 and 1,000 mg/kg body weight. There were no maternal or fetal effects noted in any of the test groups. Based on this study, both the maternal and developmental no observed effect level (NOEL) for alkyl (C<sub>12-14</sub>) polyglycosides is greater than 1,000 milligrams/kilogram (mg/kg) body weight.

4. *Subchronic toxicity*. In a sub-chronic (90-day) feeding study, test animals were treated with alkyl (C<sub>12-14</sub>) polyglycosides at doses of 0, 250, 500 and 1,000 mg/kg body weight. The only adverse effect observed in the study, in the mid (500 mg/kg) and high dose (1,000 mg/kg) groups, was reversible dose-dependent irritation and ulceration of the mucous membranes of the forestomach. Based on this study, the no observed adverse effect level (NOAEL) is 1,000 mg/kg body weight and the NOEL is 250 mg/kg/body.

5. *Animal metabolism*. Metabolism studies conducted in the mouse with closely related alkyl polyglycosides show that the -glycosidic bond of the alkyl polyglycosides is rapidly hydrolyzed in the intestine and liver. The degradates are sugars and long-chain alcohols, which then undergo carbohydrate and lipid metabolism.

6. *Metabolite toxicology*. The metabolites of alkyl (C<sub>10-16</sub>) polyglycosides are glucose and fatty alcohols, neither of which present any toxicity concerns.

7. *Endocrine disruption*. There is no information from studies conducted by the Cognis Corporation nor from the published literature which associates the alkyl polyglycosides with endocrine disruption.

### C. Aggregate Exposure

1. *Dietary exposure*. A dietary exposure assessment for alkyl (C<sub>10-16</sub>) polyglycosides has not been conducted because the alkyl polyglycosides, as a class of compounds, do not present any toxicological effects of concern. In addition, alkyl (C<sub>10-16</sub>) polyglycosides are expected to be rapidly degraded to glucose and fatty alcohols.

i. *Food*. Crop levels of alkyl (C<sub>10-16</sub>) polyglycosides have not been determined since a tolerance exemption is being requested. Moreover, even if residues of alkyl (C<sub>10-16</sub>) polyglycosides do occur on food crops these residues are of little concern since the alkyl polyglycosides are practically non-toxic.

ii. *Drinking water*. Minimal, if any, residues of alkyl (C<sub>10-16</sub>) polyglycosides are expected to occur in drinking water since alkyl polyglycosides should be rapidly (and completely) biodegraded in soils.

2. *Non-dietary exposure*. Non-dietary (residential) exposure to alkyl (C<sub>10-16</sub>) polyglycosides from the use of this substance as an inert ingredient in pesticide products is anticipated to be insignificant since only short-term exposure will be involved and dermal absorption through the skin is expected to be minimal.

### D. Cumulative Effects

No cumulative adverse effects are expected from long-term exposure to alkyl (C<sub>10-16</sub>) polyglycosides since the only affect observed in the safety studies conducted with the alkyl polyglycosides was localized irritation.

### E. Safety Determination

1. *U.S. population*. The safety studies performed with the alkyl polyglycosides clearly demonstrate that this class of compounds are practically non-toxic. The only adverse effect observed in any of the studies conducted with the alkyl polyglycosides was localized, reversible irritation of the forestomach in the sub-chronic feeding study. Consequently, the use of the alkyl (C<sub>10-16</sub>) polyglycosides as an inert ingredient in pesticidal formulations applied to growing crops is not anticipated to result in any adverse effects.

2. *Infants and children*. There is no evidence from the safety studies sponsored by Cognis, particularly the developmental toxicity study, nor from the published literature of any unique susceptibilities of infants and/or children to alkyl polyglycoside exposure. Based on the extremely low toxicity of the alkyl polyglycosides no adverse effects on infants and/or children from the use of alkyl (C<sub>10-16</sub>)

polyglycosides as an inert ingredient in pesticidal formulations applied to growing crops is anticipated.

### F. International Tolerances

There are no approved CODEX maximum residue levels (MRLs) established for residues of alkyl (C<sub>10-16</sub>) polyglycosides.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0361; FRL-7336-2]

### Bacillus thuringiensis Cry2Ab2 Protein and the Genetic Material Necessary for its Production in Cotton; Notice of Filing a Pesticide Petition to Amend a Tolerance Exemption for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2003-0361, must be received on or before January 9, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: cole.leonard@epa.gov.

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)