CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2006-4

Peroxyoctanoic acid
Tracking ID Number 214171

DESCRIPTION OF ACTION

Ecolab Incorporated submitted an application seeking California registration of Octave, EPA Reg. No. 1677-207. Octave is a sanitizer labeled for use on pre-cleaned hard non-porous food contact surfaces including pipelines, tanks, vats, filters, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. Octave contains a combination of the new active ingredient peroxyoctanoic acid in conjunction with two additional active ingredients, octanoic acid and hydrogen peroxide. Both octanoic acid and hydrogen peroxide can be found in currently registered pesticide products.

The Department of Pesticide Regulation (DPR) evaluated the product label and data and found them acceptable to support conditional registration of Octave. Precautionary and first aid statements on the product label, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide during application. DPR does not expect significant adverse environmental impacts to result from registration of Octave. The U.S. Environmental Protection Agency (U.S. EPA) conditionally registered the product under the brand name of KX-6176 on June 3, 2005. U.S. EPA's conditions of registration include the following::

1. Submit and/or cite all data required for registration of KX-6176 under FIFRA Section 3(c)(5) when U.S. EPA requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of KX-6176 under FIFRA Section 4

2. One year GLP storage stability (830.6317) and corrosion characteristics data (a830.6320), and GLP explodability data (830.6316). The storage stability study is currently under review by the U.S. EPA.

BACKGROUND

Registrant:	Ecolab Incorporated
Common name:	Peroxyoctanoic Acid
Chemical name:	Peroxyoctanoic Acid
Brand name:	Octave
Uses:	Sanitizer for hard non-porous food contact surfaces in beverage and food processing facilities
Pests controlled:	Wide variety of bacteria, including *Staphylococcus aureus, Escherichia coli*, and *Listeria monocytogenes*
Type of registration:	Conditional

Octave is a liquid formulation containing 0.94% peroxyoctanoic acid, 7.52% hydrogen peroxide, and 2.72% octanoic acid. Peroxyoctanoic acid has good bactericidal and fungicidal qualities, and belongs to the peroxyacids group of chemicals. This group of chemicals causes strong oxidation of cell membranes and other cell parts resulting in cellular death. Octave is labeled as a sanitizer for use on equipment in a wide range of food and beverage processing facilities. It is an effective sanitizer on pre-cleaned hard non-porous surfaces at 1:751 dilution in the presence of 500 ppm water hardness with a contact time of one minute.

SCIENTIFIC REVIEW

A. Chemistry

1. Product Chemistry**:** DPR evaluated the submitted chemistry studies for Octave. The results are summarized in the following table:

Table I. Physical and Chemical Properties of Octave

Properties	**Values**
Physical state	Liquid
Density (20^o)	9.23 – 10.2 pounds (lb)/gallon (gal) (Bulk)
Odor	Slightly Sharp
PH	1.90 (Undiluted Product)
Specific Gravity	1.217
Storage Stability	Not Submitted
Viscosity	198 cps
Corrosion Characteristics	Not corrosive to packaging
Color	Colorless

Submitted product chemistry data support conditional registration of Octave. The conditional registration is contingent upon the submission of an acceptable 12-month storage stability study derived from Octave.

2. Residues in Food and Animal Feed**:** Title 40 - Part 180 - Tolerance and Exemptions from Tolerance for Pesticide Chemicals in Food establishes that peroxyoctanoic acid, used in a ready to use antimicrobial pesticide formulation, for use on dairy processing equipment and food-processing equipment and utensils shall not exceed 122 ppm peroxyoctanoic acid. The label recommended dilution for Octave results in a ready to use solution of 12.5 ppm peroxyoctanoic acid.

3. Environmental Fate**:** Octave is a sanitizer labeled for use on pre-cleaned, hard non-porous surfaces including pipelines, tanks, vats, filters, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. When used as directed, DPR does not expect peroxyoctanoic acid to be released into the environment. Consequently, fish and wildlife data are not required at this time.

B. Toxicology

Ecolab Incorporated submitted adequate toxicology studies to conduct toxicological evaluations of Octave. DPR evaluated the submitted data to determine the potential for adverse health effects. The acute toxicity parameters for Octave are summarized in the following table:

Table II. Acute Toxicity of Octave

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute Oral (F)	LD_{50} 550 to 2000mg/kg	III
Acute Dermal	LD_{50} >5000 mg/kg	IV
Acute inhalation	LD_{50} >0.52 mg/l	III
Primary eye irritation*	N/A	I
Primary dermal irritation*	N/A	I
Dermal Sensitization*	N/A	N/A
Signal Word	N/A	DANGER

*The Octave primary eye and dermal irritation and dermal sensitization studies were not submitted. The product label identifies the product as being corrosive, causing irreversible eye damage and skin burns (Category I). Therefore, these data are not required at this time.

DPR's evaluation of the acute toxicity studies indicates that the studies are adequate for a complete toxicological evaluation. The product label adequately identifies the potential acute toxicity hazards indicated by the data reviewed. The first aid statements and PPE are adequate for the indicated acute toxicity hazards. DPR determined that the new active ingredient peroxyoctanoic acid can be grouped with the currently registered active ingredient, hydrogen peroxide, for the purpose of testing under the requirements of the Birth Defects Prevention Act (Food and Agricultural Code (FAC) section 13121 et al). Consequently, Birth Defects Prevention Act data are not required at this time. DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse effects, number of species affected, no effect levels (NOELs), potential for human exposure, use patterns and similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. The purpose of the risk assessment would be to appraise the potential for peroxyoctanoic acid to cause adverse health effects in humans if exposed to the pesticide as a result of legal use. At this time, peroxyoctanoic acid has not been prioritized by DPR for risk assessment. Toxicity information is not available for peroxyoctanoic acid on DPR's website. As noted above, peroxyoctanoic acid is grouped with the currently registered active ingredient, hydrogen peroxide for the purpose of testing under the requirements of the Birth Defects Prevention Act. Also, in 1995, DPR, with the concurrence of the Office of Environmental Health Hazard Assessment (OEHHA), granted pesticides containing hydrogen peroxide a waiver from the data requirements of the Birth Defect Prevention Act. The waiver was based on the fact that hydrogen peroxide is on the federal Generally Recognized As Safe (GRAS) list.

C. Health & Safety

An evaluation of the medical management information on the Octave label and the acute toxicity study results indicate that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product

label bears an adequate First Aid statement. In addition, the product label requires applicators and other handlers to wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. The product label also instructs applicators to wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, and to remove and wash contaminated clothing before reuse.

D. Fish & Wildlife

Octave is a sanitizer labeled for use on pre-cleaned, hard non-porous surfaces in dairies, dairy farms, breweries, wineries, beverage and food processing plants. Treated surfaces include pipelines, tanks, vats, filters, evaporators, pasteurizers and aseptic equipment in. When used as directed, DPR does not expect peroxyoctanoic acid to be released into the environment. Consequently, fish and wildlife data are not required.

E. Efficacy/Microbiology

Ecolab Incorporated submitted sanitizer test data derived from Octave demonstrating adequate control of *Staphylococcus aureus, Escherichia coli, Escherichia coli* 0157:H7, *Listeria monocytogenes, Salmonella typhimurium, Campylobacter jejuni, Enterobacter sakazakii, Vibrio cholerae, Saccharomyces cerevisiae, Pediococcus damnosus, Lactobacillus buchneri, Pseudomonas fluorescens,* and the fungi *Candida albicans* at 13.92 ppm peroxyoctanoic acid in the presence of 500 ppm water hardness with a contact time of 30 seconds. Submitted data are adequate to support registration of Octave.

ALTERNATIVES

Peroxyoctanoic acid is an effective sanitizer against bacteria and fungi at 13.92 ppm, which is well below the established federal limit of 122 ppm peroxyoctanoic acid for food contact surfaces. Octave has a one-minute contact time and does not require a potable water rinse. The levels of peroxyoctanoic acid residue that may remain on foods at the time of consumption do not pose a safety concern. Octave is ideal for control of bacteria and fungi on food processing equipment. There are a number of other active ingredients registered as sanitizers for use on food and beverage processing equipment. However, an effective integrated pest management strategy requires the flexibility of a large number of comparable, but not exactly equivalent, pesticides.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Octave. The label and data were found acceptable to support conditional registration. The acute health risks from human exposure to peroxyoctanoic acid are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label, and the recommended protective measures mitigate potential health risks to persons who may be exposed to these pesticides. Submitted data indicate that no significant adverse effects are expected to occur from the use of Octave, and that when used in accordance with label directions the product will be effective for the intended use. If a risk assessment conducted by DPR determines that exposure to peroxyoctanoic acid may result in unacceptable margins of exposure, further restrictions will

be placed on the use of peroxyoctanoic acid at that time. Conditional registration of Octave is recommended for one year pending the submission of an acceptable 12-month storage stability study.