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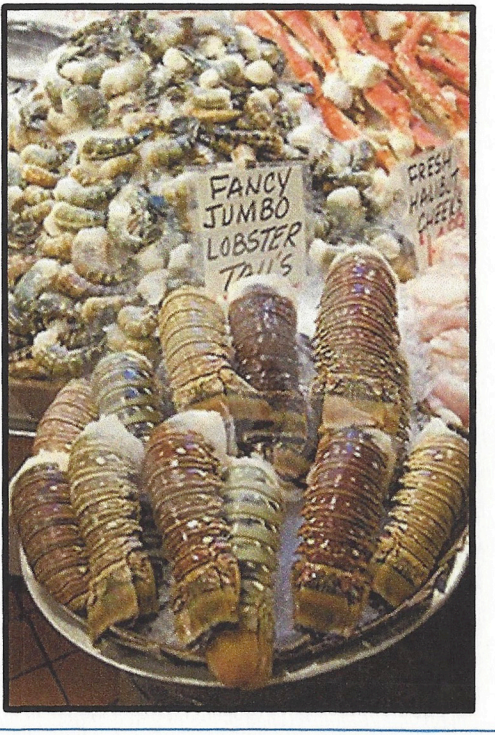
The Use of EverFresh® for Preventing Melanosis on Shrimp and Other Crustaceans

Topics

* Melanosis / blackspot development and prevention
* Composition and functionality of EverFresh®
* Comparison to alternative remedies
* Instructions for use
* Regulatory update



Blackspot or Melanosis on Crustaceans

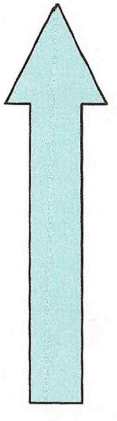
* The problems of Blackspot:

- **Blackspot or Melanosis** is the harmless but unappealing surface discoloration on shrimp, crab or lobster
- The enzyme polyphenol oxidase (PPO) is present in and under the shell of shrimp and other crustaceans and acts as a catalyst in the reaction that causes blackspot
- PPO remains active until the shrimp are frozen or cooked. The activity will resume in frozen raw shrimp upon thawing
- US quality criteria for imported shrimp calls for <1% by count on shell, <10% of the surface of each affected shrimp and 0% tolerance on meat
- **10% of a harvest** is generally thrown out because of blackspot. Less yield means less profits

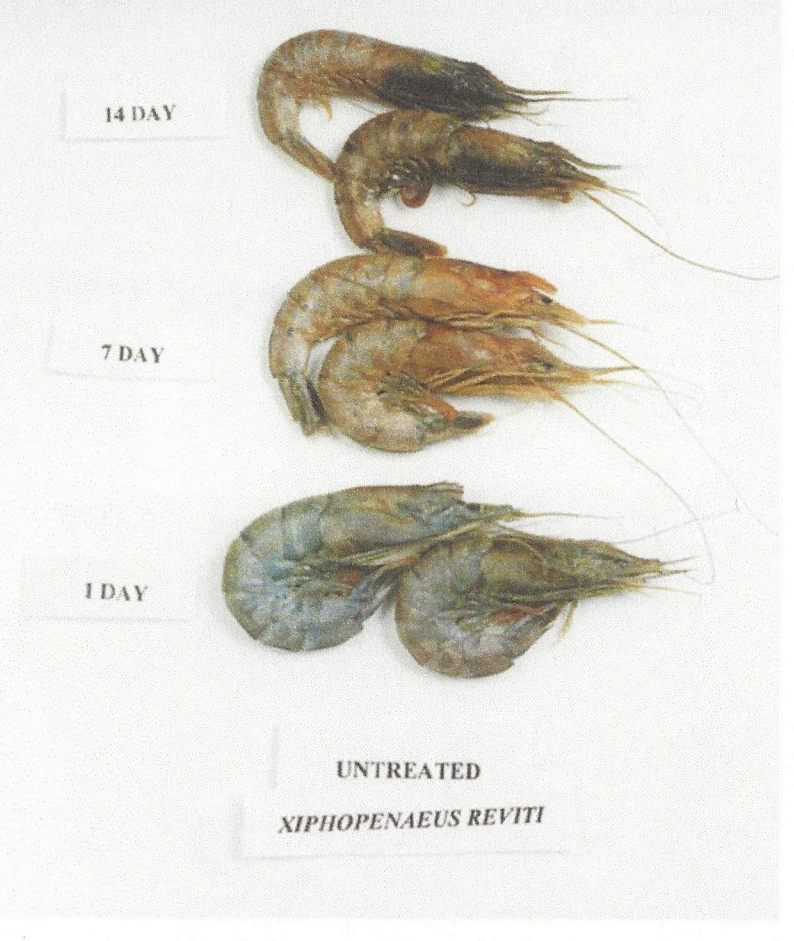
Example of Blackspot Development

* Progression of blackspot development in shrimp

Day 14

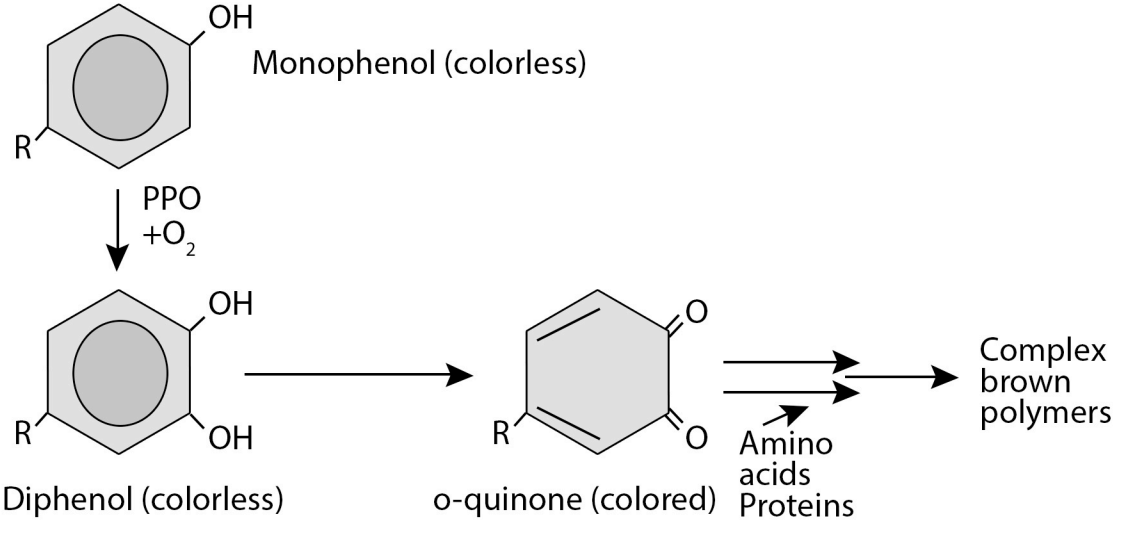


Day 1



How Blackspot Develops

* Reaction initiated by a naturally occurring enzyme polyphenol oxidase (PPO)
* In the presence of oxygen, PPO converts monophenols (colorless) to diphenols
* Diphenols are converted to highly colored quinones
* Quinones react with amino acids to form complex brown polymers



Prevention of Blackspot

* **Antioxidants:** Ascorbic acid, citric acid or erythorbic acid visually eliminate blackspot temporarily. Black color returns after thawing

* **Sulfites:** Industrial bleaching agent that masks the defect by reversing formation of quinones. **As sulfites are consumed in the reaction, repeated treatment is needed**. Sulfite is washed away upon thawing and melanosis returns

* **EverFresh®** (4-hexylresorcinol) **binds** specifically to the PPO enzyme and **renders it incapable** of catalyzing the reactions. **The effect is non reversible**

EverFresh® vs Sodium Metabisulfites

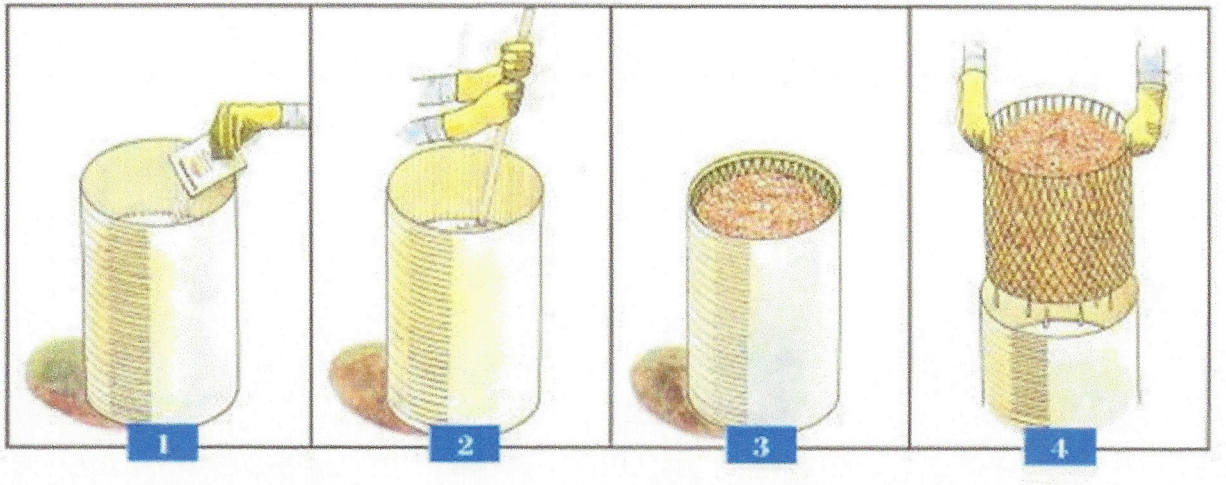
Currently, EverFresh is the only cost effective, legally permitted substitute for sulfites in shrimp.

	Sodium Metabisulfite	***EverFresh***
Functionality	▶ Bleaches blackspot ▶ Tries to reverse symptoms ▶ Repetitive treatments necessary (blackspot reoccurs after defrosting shrimp)	▶ Inhibits blackspot enzyme ▶ Blackspot never occurs – single treatment solves problem
Health Risks	▶ During handling (Sulfiting agents + moisture = Sulfure Dioxide Gas –> **Death among fisherman**) ▶ Rising number of sulfite sensitive people (asthmatics)	▶ None in the concentration applied ▶ 4 HR has been in human consumption since the 1920s – Numerous toxicological studies have been conducted
Regulatory Status	▶ Allowable sulfite residual of 100ppm on the shrimp meat	▶ **GRAS status in the US** ▶ **Compliant with EU directive for safety in food additives**
Application	▶ Sulfite dip	▶ EverFresh dip

EverFresh® - Useage

EverFresh is convenient to use:

1. Pour one premeasured pouch (200g) into 95 liters of water
2. Mix for 5 to 10 seconds
3. Dip basket with 20-25kg of shrimp into solution for 2 minutes
4. Drain



* Steps 2 and 3 may be repeated up to 10 times prior to discarding the solution

EverFresh® - Useage Cont'd

* Treat shrimp before exposing to chlorine solution or concentrated brines
* Avoid use of highly chlorinated water
* Water temperatures should be between 36°F and 81°F (2°C and 27°C)
* Never sprinkle EverFresh directly onto seafood
* Using more EverFresh or extending the time shrimp is submerged will not increase the effectiveness

Effectiveness of EverFresh®

Day 14

Day 1

Effectiveness of EverFresh®

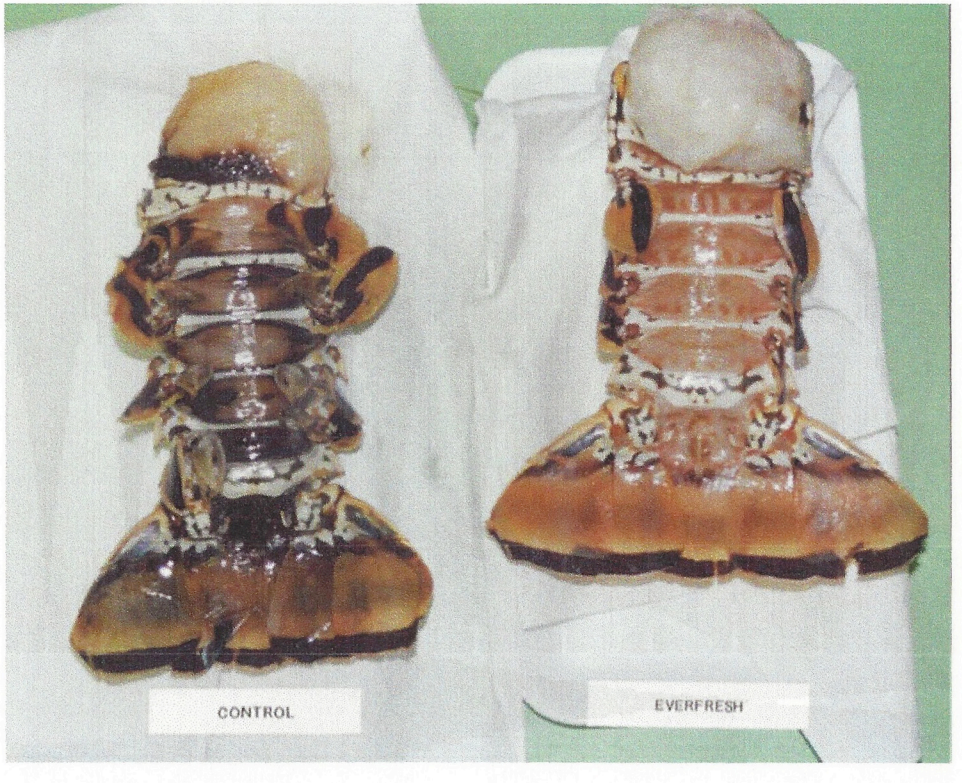
* Dipped one minute into 1.25% sodium metabisulfite, sea water, or 0.005% 4-hexylresorcinol. Photo taken after one week of storage on ice*

*McEvily, Iyengar, Otwell, Food Technology, 1991

Effectiveness of EverFresh®

* Comparison of fresh lobster tails with and without EverFresh

Untreated **EverFresh**



Effectiveness of EverFresh®

* Blackspot development can be inhibited for up to 14 days and does not reoccur after:
  - Rinsing
  - Freezing
  - Thawing
  - Refrigerating

4-Hexylresorcinol Regulatory Status

* Approved for use in the following countries
  - Australia, Canada, Columbia, Ecuador, India, Malaysia, Argentina, Brazil, Paraguay, Uruguay, Mexico, New Zealand, PR China, Thailand, United States
  - Europe: July 26, 2006: 4HR is authorized for use per directive in the Official Journal of the European Union. Each member state / country has until February 15, 2008 (18 mos) to adopt the directive into national law. In the mean time, SunOpta is pursuing temporary marketing allowances in Germany, France and Spain

Summary

* Features and Benefits
  - **EverFresh** does not only cure the symptoms, but **attacks the cause of enzymatic browning**
  - Sucessfully **prevents blackspot** from the time the shrimps are caught until they are put on your dinner plate
  - Only one treatment necessary versus repetitive treatments with sulfites to bleach away blackspot
  - **EverFresh** **increases yield** and prevents downgrading of shrimps from class I to class II shrimps
  - Unlike meta-bisulfites, there are no health risks during handling
  - Functions as a processing aid and does not require labeling on finished product

Product Information Bulletin
EverFresh®

Features and Benefits

- Prevents blackspot (melanosis) on shrimp and other crustaceans
- Safer alternative than sulfites
- Extremely effective and easy to use
- Enhances profits by increasing amount of sellable product
- Provides consistent high quality product even after thaw
- EverFresh® is a GRAS product

Applications

- Shrimp
- Prawns
- Lobster
- Other crustaceans
- Crab
- Sliced fruit

One 7.05 ounce (200g) packet of EverFresh® is needed per 25 gallons (95 liters) of water. This solution will treat 10 dip baskets at 55 pounds (25 kilograms) of shrimp (total: 550 pounds / 272 kilogram).

Physical Properties (Typical Analysis)

	EverFresh®
4-hexylresorcinol	2.16 - 2.64 %
Heavy Metals, as Pb (USP) ppm	<10

Regulatory Compliance

Ingredient Declaration:

Salt, 4-hexylresorcinol EverFresh® is a processing aid and does not require labeling on the finished package

Allergens: None

Regulatory Compliance

EverFresh® is packaged in a 7.05 ounce (200g) pouch, 16 pouches per carton (75 cartons/pallet). Storage under federal GMP guidelines will ensure an 36 month shelf life.

Certified to ISO 9001:2008
Albert-Einstein-Ring 11 . D-22761 Hamburg . Tel.:(040) 89 96 79-01 . Fax:(040) 89 96 79 12 . E-Mail: info@andenex.de

Generally Recognized as Safe (GRAS)

"GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

§170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the use of the substance is safe within the meaning of the act (see §170.3(i)). Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in this country. Persons claiming GRAS status for a substance based on its common use in food outside of the United States should obtain FDA concurrence that the use of the substance is GRAS.

(d) The food ingredients listed as GRAS in part 182 of this chapter or affirmed as GRAS in part 184 or §186.1 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in part 182, part 184 or §186.1 of this chapter.

(e) Food ingredients were listed as GRAS in part 182 of this chapter during 1958-1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in part 184 or §186.1 of this chapter.

(f) The status of the following food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to §170.35, §170.38, or §180.1 of this chapter:

(1) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, and which has been modified by processes first introduced into commercial use after January 1, 1958, which may reasonably be expected significantly to alter the composition of the substance.

(2) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, that has had significant alteration of composition by breeding or selection after January 1, 1958, where the change may be reasonably expected to alter the nutritive value or the concentration of toxic constituents.

(3) Distillates, isolates, extracts, and concentration of extracts of GRAS substances.

(4) Reaction products of GRAS substances.

(5) Substances not of a natural biological origin, including those for which evidence is offered that they are identical to a GRAS counterpart of natural biological origin.

(6) Substances of natural biological origin intended for consumption for other than their nutrient properties.

(g) A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

(h) A food ingredient that is listed as GRAS in part 182 of this chapter or affirmed as GRAS in part 184 or §186.1 of this chapter shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

(1) It complies with any applicable food grade specifications of the Food Chemicals Codex, 2d Ed. (1972), or, if specifically indicated in the GRAS affirmation regulation, the Food Chemicals Codex, 3d Ed. (1981), which are incorporated by reference, except that any substance used as a component of articles that contact food and affirmed as GRAS in §186.1 of this chapter shall comply with the specifications therein, or in the absence of such specifications, shall be of a purity suitable for its intended use. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(2) It performs an appropriate function in the food or food-contact article in which it is used.

(3) It is used at a level no higher than necessary to achieve its intended purpose in that food or, if used as a component of a food-contact article, at a level no higher than necessary to achieve its intended purpose in that article.

(i) If a substance is affirmed as GRAS in part 184 or §186.1 of this chapter with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(j) If an ingredient is affirmed as GRAS in part 184 or §186.1 of this chapter with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(k) Pursuant to §170.35, a food ingredient may be affirmed as GRAS in part 184 or §186.1 of this chapter for a specific use(s) without a general evaluation of use of the ingredient. In addition to the use(s) specified in the regulation, other uses of such an ingredient may also be GRAS. Any affirmation of GRAS status for a specific use(s), without a general evaluation of use of the ingredient, is subject to reconsideration upon such evaluation.

(l) New information may at any time require reconsideration of the GRAS status of a food ingredient. Any change in part 182, part 184, or §186.1 of this chapter shall be accomplished pursuant to §170.38.

[42 FR 14483, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984; 53 FR 16546, May 10, 1988]

Nation

Posted 2/6/2005 1:53 PM Updated 2/6/2005 1:55 PM

Report: Shrimpers continue use of questionable preservative

BROWNSVILLE, Texas (AP) — Shrimpers are still using a preservative known as "shrimp dip" despite reports of deaths and injuries because they lack a cost-effective alternative, a newspaper reported Sunday.

Shrimpers use the dip, called sodium metabisulfite, to prevent black spots from forming on the shell and legs of shrimp harvested at sea.

As many as 400 freezer boats in the Gulf of Mexico use the preservative, Harley Londrie of Zimco Marine told *The Brownsville Herald*. Londrie, who sells sodium metabisulfite to local distributors, said the chemical is safe if used properly.

The dip was blamed for 11 deaths and 32 injuries between 1970 and 1993, U.S. Coast Guard records show.

A study by the University of Texas Medical Branch in Galveston says the chemical can react under the proper conditions with water and acids from the shrimp to

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A study by the University of Texas Medical Branch in Galveston says the chemical can react under the proper conditions with water and acids from the shrimp to produce deadly clouds of sulfur dioxide.

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A shrimp boat crew member suffered permanent physical and brain damage in July 2003 due to asphyxiation caused by sulfur dioxide, his family members claim. Angel Romero Jr., of Port Isabel, has made modest improvements but remains paralyzed, said his attorney, Ray Marchan.

The family sued the shrimp boat's owners and several chemical companies, settling in the case in January for an undisclosed sum.

Shrimpers say they would welcome an affordable alternative to sodium metabisulfite but are forced to continue using it to meet the market's demand for attractive, high-quality shrimp.

Some shrimpers use another preservative named Everfresh, but others say it's too expensive and did not work well on freezer boats. Sodium metabisulfite sells for about $30 per 50-pound bag. A box of 16 packets of Everfresh, weighing just more than seven pounds, sells for $160.