

**SUBMITTED VIA E-MAIL**

March 1, 2021

National Organic Program  
USA/AMS/NOP, Standards Division  
Attention: National List Manager  
1400 Independence Ave. SW  
Room 2642-So., Ag Stop 0268  
Washington, DC 202500268

**SUBJECT:       Petition to Add Peroxylactic Acid (“PLA”) to Section 205.605 (b) of the National List**

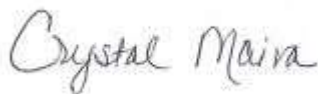
On behalf of our client, Zee Company, Inc., enclosed is a petition to add Peroxylactic Acid (“PLA”) as a processing aid for application onto meat and poultry carcasses, parts, trim, and organs. This petition follows the format described in NOP 3011 “National List Petition Guidelines Rev 01” dated March 11, 2016.

Peroxylactic acid (CAS Reg. No. 75033-25-9) is a synthetic, equilibrium product supplied by Zee Company, Inc. as an aqueous mixture for use as an antimicrobial agent in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products, in accordance with the Food and Drug Administration’s (FDA) Food Contact Notification (FCN) No. 1946. This substance also is the subject of USDA “No Objection Letter,” (Log No. 2019-75-ING) providing for the listing of peroxy lactic acid under the forthcoming revision to Food Safety and Inspection Service (FSIS) Directive 7120.1 (“Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products”). The peroxy chemistries in PLA break down rapidly to lactic acid and, ultimately, CO<sub>2</sub> and water, thereby mitigating concern that the petitioned substance will remain on organically processed food; it will not.

It is our opinion that the addition of PLA to the National List will provide meat and poultry processors with an efficacious antimicrobial intervention that offers greater safety and handling characteristics for their employees and for USDA inspectors when compared to other commercial options on the National List.

Should you have any questions or require any additional information, please contact me via email (cmaira@srconsultants.com) or phone (260.244.6270).

Sincerely,



Crystal Maira  
Agent for Zee Company, Inc.  
cc: J. Faller, Zee Company, Inc.

**Zee Company, Inc.**

**Petition to Add Peroxylactic Acid (PLA) to the National List**

**Item A.1 – National List Section for Inclusion:**

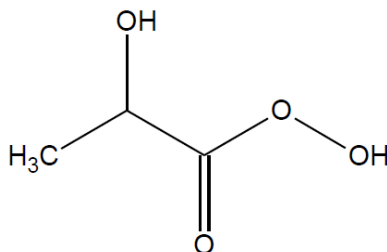
*Indicate which section or sections the petitioned substance will be included on and/or removed from the National List.*

This petition requests that a Peroxylactic Acid (PLA) be added to the National List under 7 C.F.R. § 205.605 “Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients)”.

**Item B.1 – Substance’s Chemical and/or Material Common Name:**

*Provide the substance’s chemical and/or material common name. The name of the petitioned substance should be consistent with any name(s) used by other Federal agencies (e.g., FDA, EPA, etc.)*

- IUPAC Name: 2-hydroxy-propaneperoxoic acid
- Material Common Names: Peroxylactic Acid, Perlactic Acid
- Synonym: Neotox™
- Structural Formula:



**Item B.2 – Petitioner and Manufacturer Information:**

*Provide the name, address, and telephone number for the petitioner and manufacturer (if different).*

- Zee Company, Inc.  
Attn: Jim Faller, Ph.D.  
4146 South Creek Road  
Chattanooga, TN 37406  
Phone: 423-702-7674

**Item B.3 – Intended or Current Use:**

*Describe the intended or current use of the substance, e.g., use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer, or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g. cereal, salad dressings) for which the substance will be used and a description of the substance’s function in the product(s) (e.g. ingredient, flavoring agent, emulsifier, processing aid).*

Peroxylactic acid (PLA) is used as a processing aid for application onto meat and poultry carcasses, parts, trim, and organs in food processing facilities. It is applied as an antimicrobial agent in process water, ice, or brine use in the production, processing, and preparation of raw meat and poultry products. It does not have a technical effect in finished products and therefore meets the FDA definition of processing aid in 21 CFR § 101.100(a)(3)(ii)(c). Additionally, the peroxy chemistries in the petitioned substance very rapidly breakdown to lactic acid and, ultimately, CO<sub>2</sub> and water, and as such, the petitioned substance will not persist on organically processed food.

#### **Item B.4 – Intended Activities and Application Rate:**

***Provide a list of the crop, livestock, or handling activities for which the substance will be used. If used for crops or livestock, the substance’s rate and method of application must be described.***

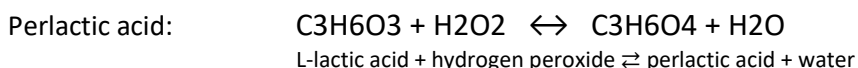
The petitioned substance is approved for use under FDA Food Contact Substance Notification (FCN) 1946<sup>1</sup>, as follows:

1. 1000 parts per million (ppm) PLA, 2384 ppm Hydrogen Peroxide (HP), and 5.5 ppm HEDP in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs; or
2. 495 ppm PLA, 1180 ppm HP, and 2.7 ppm HEDP in process water, ice, or brine that contacts processed and pre-formed meat and poultry.

#### **Item B.5 – Manufacturing Process:**

***Provide the source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.***

Perlactic acid, like peracetic acid, is supplied as an equilibrium mixture:



PLA is manufactured predominantly from hydrogen peroxide (CASRN 7722-84-1) and lactic acid (CASRN 50-21-5), both of which are cleared substances on the National List in 7 C.F.R. § 205.605(a) and 7 C.F.R. § 205.605 (b), respectively. The finished mixture optionally contains a sequestering agent 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) and an optional catalyst (sulfuric acid).

Additional information can be found in U.S. Patent 10,745,338 “Method of Peroxylactic Acid Production and Use for Reduction in Microbial Activity in Food Product Processing.”<sup>2</sup>

#### **Item B.6 – Ancillary Substances:**

***For substances petitioned for use in organic handling or processing, provide information about the ancillary substances (including, but not limited to, carriers, emulsifiers, or stabilizers) that may be included with the petitioned substance, including function, type of substances, and source, if known.***

Use dilutions of the petitioned substance may contain up to 1000 ppm PLA. Other ingredients that are proportionally present in a 1000 ppm PLA solution are hydrogen peroxide at 2384 ppm, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) at 5.5 ppm, and optionally, sulfuric acid at 13 ppm.

The optional HEDP functions as a sequestering agent for stability and the optional sulfuric acid functions as a catalyst.

#### **Item B.7 – Previous Reviews:**

***Provide a summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations. If this information is not available, this should be stated in the petition. If the substance has been previously reviewed and rejected by the NOSB, the petition must provide new information that was not submitted in an earlier petition or provided for in the previous technical reports for the substance.***

- The petitioned substance was the subject of review by the United States Patent and Trademark Office (USPTO). Review by the USPTO resulted in the issuance of U.S. Patent 10,745,338.<sup>2</sup>
- The petitioned substance has not been previously reviewed by the NOSB.

#### **Item B.8 – Regulatory Authority:**

***Provide information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. The information provided must confirm that the intended use of the substance is permitted under EPA or FDA regulations, as applicable. For food ingredients and processing aids, the substance must be approved by FDA for the petitioned use. For pesticide active ingredients, the substance must have an EPA tolerance or tolerance exemption, as applicable. If this information does not exist or is not applicable, the petitioner should state this in the petition.***

- FDA Food Contact Notification (FCN) 1946<sup>1</sup>
- USDA No Objection Letter<sup>3</sup>

#### **Item B.9 – Chemical Abstract Service (CAS) Number and Product Labels:**

***Provide the CAS number or other product numbers of the substance. If the substance does not have an assigned product number, the petitioner should state so in the petition. For food additives, the International Numbering System (INS) number should also be provided. This item should also include labels of products that contain the petitioned substance. If a product label does not apply to this substance, please provide a brief explanation. Product specification sheets, product data sheets, non-retail labels, or other product information may be substituted for the product label, if appropriate.***

- Chemical Abstract Service (CAS) Registry Number: 75033-25-9
- The Neotox™ product label is provided as **Attachment 1**.

**Item B.10 – Physical and Chemical Properties:**

***Provide the substance’s physical properties and chemical mode of action including the following – (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and/or manufacture; (d) effects on human health; and (e) effects on soil organisms, crops, or livestock.***

Peroxylic acid is a colorless liquid with a characteristic lactic acid odor and a pH of < 2 in the concentrated form, in which it is commercially sold. It has a density of 1.140 g/cm (9.519 lb/gal) and while it is miscible in water, it does not dissolve in food products, specifically meat or poultry, which is the intended food of contact for this petition. Similar to peroxyacetic acid and other oxidizing agents, peroxylic acid’s antimicrobial mode of action is thought to be the denaturation of proteins, disruption of the cell wall permeability and the oxidizing of sulfhydryl and sulfur bonds in proteins.

- a. Peroxylic acid (PLA) is anticipated to be used in food processing plants that are also utilizing peroxyacetic acid (PAA). PLA is compatible with PAA. As with PAA, PLA is not compatible with reducing agents, alkali (caustic) chemicals, or heavy metals such as iron, copper, chromium, nickel and aluminum.
- b. PLA will not persist in the environment as the peroxy chemistries in the petitioned substance very rapidly break down to lactic acid and, eventually, CO<sub>2</sub> and water. FDA also issued a Finding of No Significant Impact (FONSI) during its evaluation of FCN No. 1946<sup>4</sup>.
- c. The anticipated environmental impacts from the use and/or manufacture of PLA are as stated in item B.10.b. above.
- d. Similar to PAA, the potential effects on human health are specific to those working with PLA as there is no anticipated effect to the human health of consumers of the meat or poultry treated with PLA. Lactic acid undergoes dissociation in water to the lactate anion and the hydrated proton. The anion is subsequently rapidly biodegraded by ambient aerobic microorganisms to carbon dioxide and water. When used in accordance with FCN No. 1946, PLA is completely degraded on protein surfaces within 60 minutes.
- e. The substance will only be applied to meat and poultry products within the confines of a food processing facility and therefore, there will be no effect on soil organisms, crops, or livestock. Addition of the petitioned substance to the wastewater stream at 1000 ppm PLA will have no negative environmental impact. This is further supported by the Finding of No Significant Impact (FONSI) by FDA in the evaluation of FCN No. 1946<sup>4</sup>.

**Item B.11 – Safety Information:**

***Provide safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist or is not applicable, the petitioner should state so in the petition.***

The current Safety Data Sheet (SDS) is provided as **Attachment 2**. Zee Company does not have a substance report from the National Institute of Environmental Health Studies as Peroxylic acid will ultimately break down into carbon dioxide and water. Additional information on product safety, worker

safety, employee exposure monitoring and engineering controls can be found in the “Operational Protocol for Use of Peroxylactic Acid (FCN 1946), which is provided as **Attachment 3**.

**Item B.12 – Research Information:**

***This item should include research information about the substance. The research should include comprehensive substance research reviews and research bibliographies, including reviews and bibliographies that present contrasting positions to those presented by the petitioner in supporting the substance’s inclusion on or removal from the National List. For petitions to include nonorganic agricultural substances on the National List for organic handling, this information should include research on why the substance should be permitted in the handling of an organic product, including the availability of organic alternatives. If research information does not exist for the petitioned substance or for the contrasting petition, the petitioner should state so in the petition.***

While peer-reviewed research information does not exist for the petitioned substance, there is a wealth of information available on the precursor substances, hydrogen peroxide (CASRN 7722-84-1) and lactic acid (CASRN 50-21-5). The presence of the individual listings for lactic acid and hydrogen peroxide on the National List serve as evidence that USDA has considered the safety and suitability of these substances for combined use in an equilibrium reaction for applications described by 7 C.F.R. § 205.605(b). Similarly, the GRAS status of lactic acid, in combination with FDA’s safety assessment of perlactic acid as part of FCN 1946, demonstrates that this substance is safe for the intended use in the food-contact applications described therein.

**Item B.13 – Petition Justification Statement:**

***Provide a “Petition Justification Statement, “ which provides justification for the following action requested in the petition: “Inclusion of a Synthetic on the National List (7 C.F.R. §§ 205.601, 205.603, 205.605(b)) – Explain why the synthetic substance is necessary for the production or handling of an organic product; describe any non-synthetic substances, synthetic substances on the National List, or alternative cultural method that could be used in place of the petitioned synthetic substance; describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural method.***

The petitioner respectfully requests that peroxylic acid (PLA) be included on the National List under 7 C.F.R. § 205.605 for use as a processing aid (antimicrobial agent) for meat and poultry products. The USDA’s Food Safety and Inspection Service (FSIS) is setting new performance standards, specifically for *Campylobacter*, that will be very difficult for processors to meet in the absence of the petitioned substance. Poultry processors utilize a multi-hurdle approach in an effort to control *Salmonella* and *Campylobacter*, however, it has been well documented that *Campylobacter* infections have been increasing over the past 10 – 15 years<sup>6</sup>. Therefore, it is necessary to add another “tool” to the multi-hurdle toolbox since current intervention chemistries are not achieving the reductions necessary to control *Campylobacter*.

Microbiological studies have been conducted and demonstrate that PLA is more efficacious than PAA against *Campylobacter jejuni* and this data is provided in **Attachment 4**. While it may not be economical to fully replace PAA with PLA in poultry processing facilities, there are specific, critical intervention points where it will be highly beneficial for the organic processor to implement PLA.

Another advantage of PLA is that it has a much lower odor profile than PAA, and, consequently, it is less irritating to employees who work near the intervention application sites. Testing of PAA vs. PLA vapors above a drip tray apparatus has been performed to compare the volatility of the two chemistries. Under identical conditions and with 1000ppm use-solutions of each chemistry, a ChemDAQ Steri-Trac PAA monitor detected 10 times the concentration of PAA in the air (1.1ppm) compared to PLA (0.1ppm). This also agrees with the lower odor profile observed in PLA solutions compared to PAA solutions.

With the ever-expanding consumer interest in organic meat and poultry, the inclusion of PLA on the National List will provide those processing facilities with an antimicrobial agent that has beneficial worker safety attributes and greater efficacy against *Campylobacter* (one of the leading causes of foodborne illness in the United States) compared to the leading organic intervention chemistry, PAA. Similar to PAA, PLA is manufactured, applied and degrades in a manner that is accordance with the principles of the USDA National Organic Program and this petition is respectfully submitted for your consideration.

**Item B.14 – References:**

1. See <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN&id=1946> (Valley Chemical Solutions).
2. Bullard, R. (2020). *Method of Peroxylactic Acid Production and Use for Reduction in Microbial Activity in Food Product Processing*. (U.S. Patent 10,745,338). U.S. Patent and Trademark Office. <https://patentimages.storage.googleapis.com/2e/6a/8f/99f9a20ae76b42/US10745338.pdf>
3. September 6, 2019 No Objection Letter from Melvin Carter, Ph.D. to Jim Faller of Zee Company (Log No. 2019-75-ING).
4. See <https://www.fda.gov/media/134884/download> (FONSI for FCN 1946).
5. See <https://www.fda.gov/media/134883/download> (Environmental Assessment for FCN 1946).
6. Kaakoush, N. et al. (2015). Global Epidemiology of *Campylobacter* Infection. *Clinical Microbiology Reviews* 28(3), 687-720.

*PETITION TO ADD PEROXYLACTIC ACID (PLA) TO THE NATIONAL LIST  
ZEE COMPANY, INC.*

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**Attachment 1**

**Neotox™ (PLA) Product Label**

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# NEOTOX

## GHS INFORMATION

H272 May intensify fire; oxidizer.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H332 Harmful if inhaled.

**FIRST AID**

**After inhalation:**  
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

**After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.

**After eye contact:**  
Rinse open eye for several minutes under running water. Then consult a doctor.

**After swallowing:**  
Immediately call a doctor. Drink copious amounts of water and provide fresh air. Immediately call a doctor.

## STORAGE & DISPOSAL

Keep this and all chemicals out of the reach of children.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Dispose of in accordance with state and local regulations.

Refer to Safety Data Sheet (SDS) for additional information.

## DANGER

May intensify fire; oxidizer.

Harmful if swallowed, in contact with skin, or if inhaled.

Causes severe skin burns and eye damage.

## Hazardous Ingredients:

Peroxy lactic acid CAS# 75033-25-9

Lactic acid CAS# 50-21-5

Hydrogen peroxide solution CAS# 7722-84-1

## PRECAUTIONARY STATEMENTS

Keep away from heat/sparks/open flames/hot surfaces. Keep container tightly closed.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only in a well-ventilated area.

Wear protective gloves/protective clothing/eye protection/face protection.

**KEEP OUT OF REACH OF CHILDREN**

## USE DIRECTIONS

This product is compliant with FCNs 1946, 1995, and FSIS Directive 7120.1 and is acceptable as an antimicrobial for direct food contact on poultry and meat products. This product reduces contamination of the pathogenic bacteria like Salmonella sp. and Escherichia coli O157:H7 and other STECs on poultry and red meat carcasses, parts, trim, and organs.

**FOR MEAT AND POULTRY APPLICATIONS:** Mix with water to achieve no more than 1000 ppm peroxy lactic acid solution for use on meat or poultry carcasses, parts, trim, and organs. This can be accomplished by adding up to 63.1 fluid ounces of this product per 50 gallons of any process water, including spray, wash, dip, rinse, chiller, immersion bath, and scald waters.

## FOR PROCESSAND AND PRE-FORMED MEAT AND POULTRY PRODUCTS:

Mix with water to achieve no more than 495 ppm peroxy lactic acid solution. This can be accomplished by adding up to 31.2 fluid ounces of this product to 50 gallons of any process water, ice, or brine used to wash, rinse, store, or cool processed and pre-formed poultry products.

## IN CASE OF EMERGENCY CALL:

CHEMTREC 800-424-9300



LPL1A

**FOR SECONDARY CONTAINER USE ONLY**

NET CONTENTS \_\_\_\_\_ GALLONS

*PETITION TO ADD PEROXYLACTIC ACID (PLA) TO THE NATIONAL LIST  
ZEE COMPANY, INC.*

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**Attachment 2**

**Neotox™ (PLA) Safety Data Sheet (SDS)**

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**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 03/14/2019

Reviewed on 03/14/2019

**1 Identification**

- **Product identifier** Peroxylactic acid based antimicrobial
- **Trade name:** **NEOTOX**
- **Product code:** LPL1A
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
ZEE COMPANY, INC.  
4146 South Creek Road  
Chattanooga, TN 37406
- **Information department:** Technical Services: 423-698-1401
- **Emergency telephone number:** CHEMTREC: 800-424-9300

**2 Hazard(s) identification**

- **Classification of the substance or mixture**



Org. Perox. F H242 Heating may cause a fire.



Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.



Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 4 H332 Harmful if inhaled.

Flam. Liq. 4 H227 Combustible liquid.

- **Label elements**

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS02 GHS05 GHS07

(Contd. on page 2)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 03/14/2019

Reviewed on 03/14/2019

Trade name: **NEOTOX**

(Contd. of page 1)

- **Signal word** Danger

- **Hazard-determining components of labeling:**

peroxylactic acid  
lactic acid  
hydrogen peroxide solution

- **Hazard statements**

Combustible liquid.  
Harmful if swallowed, in contact with skin or if inhaled.  
Causes severe skin burns and eye damage.

- **Precautionary statements**

If medical advice is needed, have product container or label at hand.  
Keep out of reach of children.  
Read label before use.  
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.  
Keep/Store away from clothing/combustible materials.  
Keep only in original container.  
Wash thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
Use only in a well-ventilated area.  
Wear protective gloves/protective clothing/eye protection/face protection.  
If swallowed: Call a poison center/doctor if you feel unwell.  
If swallowed: Rinse mouth. Do NOT induce vomiting.  
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
Immediately call a poison center/doctor.  
Specific treatment (see on this label).  
Take off contaminated clothing and wash it before reuse.  
In case of fire: Use for extinction: Water spray.  
Store in a well-ventilated place. Keep cool.  
Protect from sunlight.  
Store at temperatures not exceeding 86°F. Keep cool.  
Store away from other materials.  
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 3  
Fire = 1  
Reactivity = 2

The substance possesses oxidizing properties.

- **HMIS-ratings (scale 0 - 4)**



Health = 3  
Fire = 1  
Reactivity = 2

(Contd. on page 3)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 03/14/2019

Reviewed on 03/14/2019

Trade name: **NEOTOX**

(Contd. of page 2)

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

75033-25-9	Peroxlactic acid	7.5-10.5%
50-21-5	Lactic acid	0-5%
7722-84-1	hydrogen peroxide solution	20-30%

### 4 First-aid measures

- **Description of first aid measures**
- **General information:**  
Take affected persons out into the fresh air.  
Immediately remove any clothing soiled by the product.  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**  
Remove to fresh air. If symptoms persist consult a doctor.  
In case of unconsciousness, immediately seek medical attention.  
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Remove contaminated clothing and flush area with running water for a minimum of 15 minutes. If irritation persists consult a doctor.  
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**  
Immediately flush open eye with running water for a minimum of 15 minutes. Immediately get medical attention.  
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Immediately contact a doctor or Poison Control Center.  
Immediately drink large quantities of milk, milk of magnesia, egg whites or gelatin solution. If these are not available, drink large quantities of water. Do not induce vomiting. Never give anything by mouth to an unconscious person.  
Immediately call a doctor.  
Drink copious amounts of water and provide fresh air. Immediately call a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

US

(Contd. on page 4)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 03/14/2019

Reviewed on 03/14/2019

Trade name: NEOTOX

(Contd. of page 3)

## 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**  
Do not allow to enter surface or ground water.  
Do not allow to penetrate the ground/soil.  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dike with inert materials.  
Absorb with sand or other non-combustible material.  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Use neutralizing agent.  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

50-21-5	lactic acid	5 ppm
75033-25-9	peroxylactic acid	0.52 mg/m <sup>3</sup>
7722-84-1	hydrogen peroxide solution	10 ppm

- **PAC-2:**

50-21-5	lactic acid	35 ppm
75033-25-9	peroxylactic acid	1.6 mg/m <sup>3</sup>
7722-84-1	hydrogen peroxide solution	50 ppm

- **PAC-3:**

50-21-5	lactic acid	250 ppm
75033-25-9	peroxylactic acid	15 mg/m <sup>3</sup>
7722-84-1	hydrogen peroxide solution	100 ppm

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.

(Contd. on page 5)

US

# Safety Data Sheet

acc. to OSHA HCS

Printing date 03/14/2019

Reviewed on 03/14/2019

Trade name: NEOTOX

(Contd. of page 4)

- Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Do not store in direct sunlight.  
Store in a cool, dry, well ventilated area.
- **Information about storage in one common storage facility:**  
Store away from flammable substances.  
Store away from reducing agents.
- **Further information about storage conditions:**  
For quality purposes, avoid temperatures in excess of 86 degrees F. Elevated temperatures will accelerate decomposition resulting in a loss of assay.  
Shelf life: 6 months at ideal storage conditions  
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

### 50-21-5 lactic acid

PEL	Long-term value: 25 mg/m <sup>3</sup> , 10 ppm
REL	Short-term value: 37 mg/m <sup>3</sup> , 15 ppm Long-term value: 25 mg/m <sup>3</sup> , 10 ppm
TLV	Short-term value: 37 mg/m <sup>3</sup> , 15 ppm Long-term value: 25 mg/m <sup>3</sup> , 10 ppm

### 75033-25-9 peroxy lactic acid

TLV	Short-term value: 1.24* mg/m <sup>3</sup> , 0.4* ppm *inhalable fraction + vapor
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### 7722-84-1 hydrogen peroxide solution

PEL	Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm
REL	Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm
TLV	Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Breathing equipment:**  
Not necessary if room is well-ventilated.  
Use suitable respiratory protective device with organic acid cartridge in case of insufficient ventilation.

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- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Apron

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

· <b>Form:</b>	Liquid
· <b>Color:</b>	Colorless
· <b>Odor:</b>	Characteristic
· <b>Odor threshold:</b>	Not determined.

- **pH-value at 20 °C (68 °F):** <2

- **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

- **Flash point:** >55 °C (>131 °F)

- **Flammability (solid, gaseous):** Not applicable.

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

· <b>Lower:</b>	Not Determined
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<b>Upper:</b>	Not Determined
· <b>Vapor pressure at 20 °C (68 °F):</b>	Not determined.
· <b>Density at 20 °C (68 °F):</b>	1.140 g/cm
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Fully miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	No further relevant information available.

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**  
Stability decreases with concentration, heat, light exposure, decrease in pH and contamination with heavy metals such as nickle, cobalt, copper, and iron.
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions**  
Acts as an oxidizing agent on organic materials such as wood, paper and fats.  
Reacts with reducing agents.  
Reacts with strong alkali.
- **Conditions to avoid**  
Open Flames, elevated temperatures, any source of heat, combustibles such as paper and wood, and contamination. Temperatures above 86 degrees F will decrease shelf life of product and accelerate decomposition resulting in a loss of assay.
- **Incompatible materials:**  
reducing agents, oxidizing agents, organics, heavy metals such as iron, copper, chromium, nickel, aluminum, and cobalt.  
Alkali (Caustic)
- **Hazardous decomposition products:** No dangerous decomposition products known.

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## 11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

**50-21-5 lactic acid**

Oral	LD50	3,310 mg/kg (rat)
Dermal	LD50	1,060 mg/kg (rabbit)

- **Primary irritant effect:**

- **on the skin:** Strong caustic effect on skin and mucous membranes.

- **on the eye:** Strong caustic effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful

Corrosive

Irritant

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

7722-84-1	hydrogen peroxide solution	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Danger to drinking water if even small quantities leak into the ground.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

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· **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

· **Waste treatment methods**· **Recommendation:**

Dispose of in accordance with federal, state, and local regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**· **Recommendation:** Disposal must be made according to official regulations.· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

## 14 Transport information

· **UN-Number**· **DOT, IMDG, IATA**

UN3109

· **UN proper shipping name**· **DOT, IMDG**· **IATA**

Organic peroxide type F, liquid

ORGANIC PEROXIDE TYPE F, LIQUID

· **Transport hazard class(es)**· **DOT**· **Class**

5.2 Organic peroxides

· **Packing group**· **DOT**

II

· **Environmental hazards:**· **Marine pollutant:**

No

· **Special precautions for user**

Not applicable.

· **Stowage Category**

D

· **Stowage Code**

SW1 Protected from sources of heat.

· **Segregation Code**

SG35 Stow "separated from" acids.

SG36 Stow "separated from" alkalis.

SG72 See 7.2.6.3.2.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**· **DOT**· **Quantity limitations**

On passenger aircraft/rail: 10 L

On cargo aircraft only: 25 L

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- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>· <b>IMDG</b></li> <li>· <b>Limited quantities (LQ)</b></li> <li>· <b>Excepted quantities (EQ)</b></li> </ul> | <p>125 ml<br/>Code: E0<br/>Not permitted as Excepted Quantity</p> |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>  | -   |

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

75033-25-9	peroxylactic acid
7722-84-1	hydrogen peroxide solution

- **Section 313 (Specific toxic chemical listings):**

75033-25-9	peroxylactic acid
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- **TSCA (Toxic Substances Control Act):**

50-21-5	Lactic acid	ACTIVE
7722-84-1	Hydrogen peroxide solution	ACTIVE

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

7722-84-1	hydrogen peroxide solution	A3
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- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

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- **GHS label elements**

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The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS02 GHS05 GHS07

- **Signal word** Danger

- **Hazard-determining components of labeling:**

peroxylactic acid

lactic acid

hydrogen peroxide solution

- **Hazard statements**

Combustible liquid.

Harmful if swallowed, in contact with skin or if inhaled.

Causes severe skin burns and eye damage.

- **Precautionary statements**

Keep out of reach of children.

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Keep/Store away from clothing/combustible materials.

Keep only in original container.

Do not breathe dusts or mists.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only in a well-ventilated area.

Wear protective gloves/protective clothing/eye protection/face protection.

Immediately call a poison center/doctor.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: Water spray.

Store in a well-ventilated place. Keep cool.

Protect from sunlight.

Store at temperatures not exceeding 86°F. Keep cool.

Store away from other materials.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Contact:** Jim Faller

- **Date of preparation / last revision** 03/14/2019 / 18

- **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety &amp; Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 4: Flammable liquids – Category 4

Org. Perox. F: Organic peroxides – Type E/F

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

**\* Data compared to the previous version altered.**

US

*PETITION TO ADD PEROXYLACTIC ACID (PLA) TO THE NATIONAL LIST  
ZEE COMPANY, INC.*

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**Attachment 3**

**Operational Protocol for Use of Peroxylactic Acid (FCN 1946)**

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## OPERATIONAL PROTOCOL FOR USE OF PEROXYLACTIC ACID (FCN 1946)

### **History and Conditions of Use**

As a result of marketplace expectations and continually tightening USDA regulations for antimicrobial control and concern for worker safety, Zee Company, Inc. has developed a new chemistry, FCN 1946, which is both more antimicrobially efficacious and presenting a much lower odor profile than peroxyacetic acid (PAA). This FCN is an aqueous mixture of peroxylic acid, hydrogen peroxide, acetic acid, optional sulfuric acid, and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

Uses and concentrations permitted by FCN 1946:

1. 1000 parts per million (ppm) PLA, 2384 ppm HP, and 5.5 ppm HEDP in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs; or
2. 495 ppm PLA, 1180 ppm HP, and 2.7 ppm HEDP in process water, ice, or brine that contacts processed and pre-formed meat and poultry.

### **The technology will not adversely affect the safety of meat and poultry products.**

PLA has heretofore played a minimal role in the commercial marketplace. A primary reason for its lack of commercial viability has been producing it in sufficient quantity to be practical and economical enough for general use. Zee Company, Inc. has developed a manufacturing process that permits the creation of a 10% active PLA solution that can diluted down to effective antimicrobial levels for use.

Laboratory studies have consistently demonstrated higher efficacy against food pathogens with PLA than PAA at similar concentrations and will provide an opportunity for meat and poultry processing plants to maintain compliance with ever-increasing regulatory requirements designed to ensure food safety.





## **Operating Conditions at the Establishment**

### **1. Concentration and pH of the antimicrobial chemistry**

FCN 1946 will be added to tap water via an in-line injection systems used to fill and maintain various dip and spray applications and maintain concentrations of PLA at the use site in concentrations ranging from 10 – 1000 ppm PLA.

FCN 1946 is antimicrobially efficacious in a pH range from ~0.5 -- ~10.0. Food pathogens may be respond more favorably to PLA at different pH's, and there should be no pH restriction to its application.

Concentration levels of PLA at the use locations will be monitored using an appropriate test kit provided by Zee Company, Inc. Likewise, pH may be monitored by use of a pH meter or pH strips.

### **Contact time and spray pressure**

FCN 1946 solutions will be applied similarly to currently used PAA solutions at contact times appropriate to the antimicrobial intervention site in meat and poultry processing plants in which they are used. It is anticipated that lower concentrations of PLA will result in higher contact times and higher concentrations may achieve efficacy in much lower contact times.

Typical contact times for various uses in meat and poultry processing: Spray: 2 – 60s at 3 – 350 psi, depending on application.

Dip (excluding poultry main and secondary chillers, and otherwise FSIS approved uses, like OLR dip): 3 – 180s depending on application.

### **2. Water Temperature**

Water temperature does not affect the efficacy of PLA solutions, and



temperatures in the range of 32° - 130° F should be considered an appropriate and effective antimicrobial.

### **3. Reuse of PLA solution**

Overflow and/or drip water may be collected and used in antimicrobial intervention sites upstream from any particular intervention site. If the PLA solution is reused in these locations, the solution will be reconditioned in accordance with 9 CFR 416.2(g).

### **4. Safety**

#### **1. Product Safety**

FCN 1946 will be transported to meat and poultry processing plants in DOT approved drums or totes. The product will be stored in a chemical storage area, away from USDA and plant employees. Product will be diluted with plant potable water using an automated in-line dosing system prior to being introduced at a particular antimicrobial intervention site. Zee Company, Inc. will provide instruction on safe handling and dispensing of this product and help ensure that its use complies with all plant safety rules.

#### **2. Worker Safety**

PLA is a new chemistry in the food processing industry. Zee Company expects that PLA will be used as a replacement for PAA in many applications. Advantageously, PLA has a much lower odor profile than PAA and, consequently, will be less irritating to employees who work near intervention sites. Under conditions of use specified by Zee Company, contact with the concentrated product is minimized for plant personnel, and all but impossible for USDA staff. Containers of concentrate are stored far from the processing floor. Closed, automated injection systems are utilized to introduce concentrate into water lines that feed desired concentrations of this product to various application sites throughout the plant, including into spray cabinets and dip tanks.

Use dilutions of this product may contain up to 1000 ppm PAA. Other ingredients that are proportionally present in a 1000 ppm PLA solution are Hydrogen peroxide at 2384 ppm, HEDP at 5.5 ppm, and, optionally, Sulfuric acid at 13 ppm. All of these chemistries are heavier than water and have very little potential to be aerosolized and remain in the air for long periods of time. In fact, PLA is 1.4 times heavier than PAA. Should atomization of this product occur, it might possibly produce very low level vapors that may contain some of each of these chemistries but, unless they are permitted to concentrate in an unventilated area, they will be at such low levels that little or no



health effects are anticipated. There are currently no known established or proposed limits for exposure to PLA in air. Considering the similarities of the chemistry and the considerably lower odor profile of PLA, we propose that PLA concentrations be maintained below the currently acceptable limit of PAA of 0.4 ppm PAA. At this level there might also be only 0.95 ppm Hydrogen peroxide, 2.2 ppb HEDP, and 5.2 ppb Sulfuric acid in the air – levels far below those that would be of concern for human health hazards.

Testing of PAA vs. PLA vapors above a drip tray apparatus has been performed to compare the volatility of the two chemistries. Under identical conditions and 1000ppm solutions of each chemistry, a ChemDAQ Steri-Trac PAA monitor detected 10 times the concentration of PAA in the air (1.1ppm) compared to PLA (0.1ppm). This also agrees with the lower odor profile observed in PLA solutions compared to PAA solutions.

While the use solutions are considered to be able to be used in a manner that will not compromise employee health, contact with concentrated product should be avoided. Severe burns are expected from dermal contact with the concentrate, and inhalation of concentrated fumes might trigger respiratory distress.

It is unexpected that USDA staff would ever need to be exposed to concentrated product but there may be some potential for direct contact with use dilutions in both spray cabinets and dip tanks. Exposure to drippage from carcasses is minimized by the use of drip pans under overhead transport systems and by wearing smocks, hard hats, and other occlusive apparel. Exposure to overspray from spray cabinets should be minimized by cabinet design and ventilation. Contact exposure by USDA staff may be possible if an inspector handles poultry immediately after it has been treated with PLA solutions. However, any potential health impact resulting from this exposure can be entirely mitigated by the use of gloves. Latex and nitrile gloves, both commonly used in food processing plants, are impervious to PLA.

It is possible that, as with PAA, some people may experience contact dermatitis due to PLA exposure. Contact can be minimized or eliminated by using gloves whenever there is a need to be potentially exposure to PLA solutions. Additionally, because PLA, like most chemistry, may be an eye irritant, eyes should be protected with safety glasses if contact appears to be possible. Effects of exposure to use dilutions should be easily controlled by washing eyes and skin with water should contact occur.

At higher concentrations of PLA there is a possibility of generation of a perceptible, but non-irritating, odor in the vicinity of an application site. This odor is most likely to occur with spray applications where, if pressure is excessive, impact of the spray with a carcass may cause aerosolizing of the chemistry. Since no impinging impact is created in a dip tank applications, the potential for aerosolization is not anticipated.



People with respiratory health conditions, such as asthma, are often susceptible to irritation from many odors and may experience discomfort upon exposure to the mild odor created by concentrated PLA use solutions. General plant ventilation is usually enough to relieve irritation.

### **3. Employee Exposure Monitoring**

As noted earlier in this document, exposure limits in air are not established for PLA or lactic acid. Hydrogen peroxide has a TWA OSHA PEL of 1 ppm. No monitoring equipment for PLA exists, but Zee Company suggests that, due to chemical similarity, a PAA monitor may provide assurance that exposure to elevated air concentration levels of this chemistry are not concentrating at an intervention site. Using a PAA monitoring device calibrated to the established 0.4 ppm PAA limit provides a repeatable means for evaluating PLA concentration. In plants that utilize this detection technology, if the alarm sounds, USDA personnel should exit the area until it is properly ventilated and returned to a condition below the 0.4 ppm PAA TLV.

### **4. Engineering Controls**

The primary means of controlling vapors that may be created when using PLA products is ventilation. Zee Company recommends that its customers maintain adequate ventilation at PLA antimicrobial intervention sites to prevent build-up of vapors in the air that exceed ACGIH recommendations for PAA. If control cannot be maintained with ambient ventilation Zee Company recommends that increased local ventilation be utilized to maintain acceptable air quality. Zee Company always partners with its food processing customers to ensure the safe use of its products.

Plants are encouraged to determine PLA concentration in air by use of a PAA monitoring device. Zee Company is a distributor of ChemDAQ's Steri-Trac PAA detection monitoring system. These highly sensitive and accurate devices continuously monitor air for PAA concentration and are designed to alarm if the concentration exceeds 0.4 ppm. Although there is no established PEL for PLA, Zee Company recommends that, due to chemical similarity, the PAA concentration level be used for monitoring purposes.

At this time, Zee Company is unaware of any processing plant using its products that has not been successfully able to control chemical vapors with ambient ventilation. Apart from adequate ventilation other engineering controls may also help control PLA vapors



in plants. In spray applications, the presence of splash shields aid in prevention of PLA solutions being sprayed into the plant environment. Proper nozzles and pressure controls in the spray cabinets ensure a drenching spray that thoroughly wets carcasses/parts, but does not impinge so hard on the carcasses/parts that aerosolization of PLA solutions occurs.

Dip tank PLA solutions are fed by water/antimicrobial injection lines that deliver right at, or below, the surface of the water, minimizing splashing. The water is not aerosolized or micronized, minimizing the development of any mist.

Discharge from spray cabinets may be collected and diverted upstream for use at another antimicrobial intervention site. More commonly, the solution is directed to drain and is mixed with other processing waste stream components as it exits the plant. PAA product rapidly degrade in this environment into acetic acid and water, resulting in an innocuous discharge. Mixture of dilute PAA and its degradation products with other dilute chemistries that may be present in the waste stream have not, in Zee Company's experience, ever resulted in a hazardous incident in any of its processing plants.

Discharge from dip tanks will occur in two ways: 1) as drag-out on the carcasses and 2) deliberately when the tank is emptied for sanitation procedures. For drag-out, there is no difference between a sprayed or a dipped carcass dripping on the line

before it enters the chiller. Some antimicrobial chemistry will be introduced into drip pans under the line and that chemistry will be dumped to the waste stream in the drain or back into the dip tank. In fact, there will probably be a reduction in chemistry dumped to drain from the dip application because overspray from spray applications is usually not captured for reuse, but dumped to drain. The probable worst case scenario is a net zero difference between the two application methods in terms of discharge of excess, but more likely, the dip method will generate less excess. For tank emptying for sanitation, the antimicrobially treated water left in the tank at the end of processing will be dumped directly to drain just like the water from every other processing application, including large chiller tanks. Again, at worst, a net zero difference in the volume of chemistry will be introduced into the waste stream. Exposure to antimicrobial chemistry is minimized as it currently is in other dip tank applications -- by directing the water through pipes or hoses to a floor drain and by minimizing production personnel (including USDA personnel) in the areas where sanitation has begun.



## 5. Environmental Safety

Addition of FCN 1946 to the waste stream at  $\leq 1000$  ppm PLA will have no negative environmental implications. The peroxy chemistries in FCN 1946 very rapidly break down to lactic acid and, eventually, CO<sub>2</sub> and water with negligible environmental impact. HEDP, a chemistry of environmental concern in higher concentrations, will only be present in the waste stream at  $\leq 5.5$  ppm in treated water, a level found to be insignificant by FDA in terms of environmental safety.

For:  
ZEE COMPANY, INC.

A handwritten signature in black ink, appearing to be "J. Faller", written over a light gray horizontal line.

Jim Faller, PhD  
Technical Director

*PETITION TO ADD PEROXYLACTIC ACID (PLA) TO THE NATIONAL LIST  
ZEE COMPANY, INC.*

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**Attachment 4**

**Neotox™ (PLA) Microbiological Testing Summary**

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November 12, 2019

## MICROBIOLOGICAL TESTING SUMMARY

Comparative studies were performed to determine the potential differences in the antimicrobial efficacy of use-solutions prepared from a commercially available peracetic acid product (PAA) and from Neotox (PLA).

Commercially available chicken legs were exposed for ~ 30 mins. to either a culture of *Salmonella Infantis*, grown to  $\sim 10^6$  in Nutrient Broth or a culture of *Campylobacter jejuni*, grown to  $\sim 10^6$  in Brucella Broth. Dilutions of each product at 400 ppm active were prepared as test solutions for the testing vs. *S. Infantis* and at 800 ppm and 500 ppm active for the testing vs. *C. jejuni*.

Microbially contaminated chicken legs were immersed into the specified test solution for a period of 15s and then removed from the bag and allowed to drip for 15s. The legs were then vigorously shaken in a solution of nBPW for 60s to neutralize the PAA or PLA and to release bacteria from the surface of the chicken legs.

Serial dilution testing of the nBPW solution revealed that at the same use-concentrations, PLA was statistically more efficacious than PAA under the conditions of this test. The results are summarized in the tables below.

TEST SUBSTANCE	Average Log <sub>10</sub> Reduction of <i>S. Infantis</i>
Neotox (400 ppm PLA solution)	1.13
PAA product (400 ppm PAA solution)	0.44

TEST SUBSTANCE	Average Log <sub>10</sub> Reduction of <i>C. jejuni</i>
Neotox (800 ppm PLA solution)	1.20
PAA product (800 ppm PAA solution)	0.68
Neotox (500 ppm PLA solution)	0.82
PAA product (500 ppm PAA solution)	0.48

For:  
Zee Company, INC.

James Faller, Ph.D.  
Technical Director