EPA

Region 8

DRAFT Strategy

Addendum to the Region 8 Local Limits Strategy

Discharges of Wastewater to Publicly-Owned Treatment Works (POTWs) from Pathology/Necropsy and Research Facilities Working With Tissues Contaminated with Transmissible Spongiform Encephalopathy (TSE) Agents

August 28, 2006

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This document was distributed to EPA Region 8 POTWs in Draft form.

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I. Summary and Background

The Industrial Pretreatment Program is authorized under the Clean Water Act and implemented through regulations found at 40 CFR Part 403, General Pretreatment Regulations for New and Existing Sources of Pollution. The objectives of the Pretreatment Program are to *prevent* discharges to a publicly-owned treatment works (POTW) that may cause pass through of pollutants to receiving waters, interfere with POTW operations, cause adverse effects to worker health and safety or interfere with the ability to recycle or reclaim biosolids. EPA and authorized states require all POTWs to take specific actions to protect their sewerage systems and treatment works from discharges from industrial, commercial or government non-domestic sources that may cause a violation of the General or Specific Prohibitions found at 40 CFR Section 403.5, including violations of any local limits established by the local government. In some cases, EPA requires the POTW to develop a specific program called an Industrial Pretreatment Program, to control these indirect discharges to its POTW. The POTW has the legal authority to evaluate non-domestic discharges, inspect facilities, issue permits, prohibit discharge, enforce pretreatment standards and requirements, and require treatment prior to discharge to the POTW.

The Industrial Pretreatment Program is a preventative program that enables EPA, authorized states and POTWs to implement procedures to meet the objectives of the program. This includes taking actions to prevent contaminants that may impact the POTW, human health and the environment from being released into sewerage systems. This Strategy is a guide for pretreatment programs to ensure that discharges from testing, diagnostic, research and necropsy labs are allowed only in full compliance with the Clean Water Act and its implementing regulations.

The purpose of this document is to provide guidance for Industrial Pretreatment Programs which accept laboratory wastewaters from facilities that work with Transmissible Spongiform Encephalopathy (TSE) contaminated tissues. In this Strategy the common term “prion” is used to mean “TSE agent”. This guidance will use the term TSE agent to refer to those prions that have been implicated as causing animal and human health diseases. There are two wastewater discharges that may be of concern for POTWs: chemical pollutants, and tissues containing TSE agents that have not been inactivated. This guidance will identify current Best Management Practices (BMPs) intended to minimize the entry of active TSE agents and excessive concentrations of chemical pollutants into the sewerage system.

EPA recognizes that other business sectors may process animals that contain TSE agents. Further guidance to POTWs may be developed.

Facilities may discharge wastewaters to other wastewater disposal systems. Discharges to leach fields generate solids and liquid waste in septic tanks. Septic tanks intercept waste prior to draining to the leach field. POTWs are commonly used for the disposal of septic tank wastes. The discharge of these trucked and hauled wastes are regulated under the Pretreatment Program; whereas, discharge of the wastewater to a leach field is regulated by the Underground Injection Control Program [(1)].

II. Publicly-Owned Treatment Works (POTWs)

TSE agents can survive for extended periods of time in the environment. Common methods of waste water treatment and disinfection of effluent from the POTW (chlorination and UV disinfection) and biosolids composting appear to be ineffective at inactivating TSE agents. No analytical test is currently available for measuring TSE agent concentrations in wastewater discharged to or from POTWs, surface water or biosolids. Until such tools are developed, controlling the discharge of TSE agent contaminated wastewater to the POTW is best accomplished by treatment and/or Best Management Practices (BMPs).

Such measures can effectively minimize discharges containing TSE agents to POTWs and the environment. However, the chemicals used for inactivation of the TSE contaminated tissues and surfaces may be harmful to the POTW and must be evaluated with care.

Three main waste streams leave POTWs. They are air emissions, effluent discharged to Waters of the United States and biosolids produced as a result of solids removal and treatment at the POTWs. Based on current knowledge, there is no identified wastewater treatment process at a POTW that is effective at completely inactivating TSE agents. Although little information exists on the partitioning of TSE agents in wastewater treatment, some general predictions can be made. Based on limited understanding of TSE agent behavior in environmental media, TSE agents are expected to partition primarily to the solids; the highest concentrations would be expected to occur in the biosolids rather than the liquid fraction. There are currently no data on the extent to which TSE agents would be expected to partition into the effluent. TSE agents would not be expected to be present in air emissions from wastewater treatment works since they are not volatile.

Biosolids are typically applied to food and non-food crops, as well as range land. The recycling and beneficial reuse of biosolids is one of EPA's objectives under the Clean Water Act and a major priority of POTWs. In Region 8 states, land application of biosolids is economically feasible because of the vast open space and arid climate. Biosolids may be a valuable nutrient supplement to clay or nutrient poor soils. Significant amounts of biosolids are composted and sold as a soil conditioner for home gardens and yards.

III. Laboratory Discharge Practices to POTWs

A number of laboratories in Region 8 work with animal diseases and discharge pollutants to POTWs. The development of this Strategy arises from the need to address discharges to POTWs from laboratories in Region 8 that work with tissue that may contain TSE agents. The majority of facilities that work with TSE agents in Region 8 work primarily with the chronic wasting disease (CWD) TSE agent. The bulk of the wastewater discharged by these facilities is from CWD necropsy, research and testing activities. CWD has not been shown to be a human pathogen. There may be additional TSE disease research or testing laboratories in Region 8 that have discharge practices and pollutants that are similar to the CWD laboratories (e.g. Bovine Spongiform Encephalopathy (BSE), scrapie, transmissible mink encephalopathy (TME), etc). If a laboratory is working with known human TSE agents (e.g. BSE, Creutzfeldt-Jacob disease (CJD), variant Creutzfeldt-Jacob disease (vCJD)), the POTW should consider instituting more rigorous discharge controls and/or treatment requirements. Laboratories working with human TSEs, any TSE propagated in apes and monkeys or BSE are maintained at CDC Biosafety Level 2 or 3, whereas, laboratories working with animal TSEs are maintained at CDC Biosafety Level 2 [(2)]. This Strategy provides guidance on waste water management and potential pollutants of concern that may be generated from a facility that works with TSE contaminated materials.

A. General

There are two wastewater discharges that may be of concern for POTWs: chemical pollutants, and tissues containing TSE agents that have not been inactivated. Laboratories utilize two general wastewater management approaches:

1. The first are those technologies implemented to treat the entire TSE agent contaminated wastewater stream leaving the laboratory regardless of the presence of solids or tissues (segregation, containment and treatment of wastewater). Treatment technologies associated with

this approach includes high temperature incineration and alkaline hydrolysis. These technologies, when properly operated, are the most effective at inactivating TSE agents in wastes, assuring that active TSE agents are not released to the POTW. Incinerators typically have no discharge to a POTW (unless equipped with a scrubber), whereas the alkaline hydrolysis treatment systems generate an effluent that may discharge to a POTW. One waste minimization technique that can be implemented is dehydration of the alkaline hydrolysis effluent, resulting in zero discharge status for these wastes to the POTW. Where a laboratory employs segregation, containment and treatment of wastewater, the POTW should request the facility to document the practice and verify the information through on-site inspections.

2. The second general approach is the segregation of some waste streams (primarily solids) for off-site disposal and the discharge of wastewaters that are relatively free of solids. Three wastewater streams may be identified:

   a. Blood and other tissues where animals are processed.

   b. Detergents, water and/or solids generated from the cleaning step prior to final inactivation treatment and wash. This waste stream would contain active TSE agents if any processed animal or tissue was infected.

   c. Chemicals used in the inactivation treatment of prions and final wash waters. The chemical treatment for TSE agent inactivation is an EPA registered product used according to terms and conditions of approval by EPA under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Currently, Environ LpH® is approved through Section 18 Emergency Exemptions for use in the inactivation of various TSE agents. For further information see Section III.B.2. and Attachment B. Sodium hydroxide and sodium hypochlorite may also be used for disinfection by some labs and are discussed throughout this document. Additional FIFRA approvals for inactivation agents other than Environ LpH® may become available.

3. The primary sources of laboratory discharges to a POTW discussed in subsequent sections of this Strategy may include:

   a. Floor drains in necropsy and laboratory work areas;
   b. Surface treatments (floors and work surfaces) that are cleaned, decontaminated and washed to the drains;
   c. Sinks used to wash, soak, or otherwise clean equipment;
   d. Discharge of pumped septic tank waste;
   e. Alkaline hydrolysis treatment units; and
   f. Discharge from incinerator scrubber water.

As a part of the Industrial Waste Survey (IWS), the POTW should require facilities working with tissues that may be contaminated with TSE agents to fully characterize the following facility information:

   a. Detailed Best Management Practices (BMPs) that are implemented
   b. Initial tissue removal procedures
   c. Surface treatment practices
   d. Discharge practices
   e. Plumbing schematics
   f. Treatment (other than surface treatment) that is employed and waste streams generated

B. Laboratory Procedures

Effective TSE agent inactivation necessitates the removal of tissue residuals and debris from work areas, treatment with an inactivating agent, and removal of the residual inactivating chemical. Facilities may perform some or all of these steps and may combine some steps. Tissue removal steps do not result in TSE inactivation. Inactivation is primarily conducted on a surface after solids are removed.

1. Surface Cleaning of Solids

The surface cleaning step may include:

a. Mechanical cleaning (e.g. scraping material from surfaces, broom, squeegee, etc.). Mechanical cleaning can be achieved with the generation of minimal wastewater. This approach is recommended because it minimizes the possibility of contaminated tissue (solids) discharge prior to inactivation. If there are TSE agents present, it may be advisable to keep the surface wet while cleaning this material to minimize aerosolization of the TSE agent.

b. Use of treatment chemicals, detergents, water and physical abrasion (where needed). Minimal volumes of surface and floor wash water should be used during necropsy and clean up.

If the discharger washes the floor as a part of the pre-cleaning step, the discharger should manage the wastewater as required by the POTW (e.g. screens or filters to remove solids, installation of adequate containment, proper design of treatment, etc.). The use of screens to minimize solids entering the sewerage system is discussed in Section III.D.

2. Treatment to Inactivate Prions

The US Environmental Protection Agency has approved Section 18 Emergency Exemptions for the use of Environ LpH® to inactivate TSE agents. In Region 8, Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming have received approval for use of Environ LpH® for selected TSEs as of the date of this Strategy. The lead agency in each state (generally the state Department of Agriculture) should be contacted for an example of the approvals for that state. The approvals, by state, are as follows:

State	Effective Date	Expiration Date	TSEs covered
Colorado	3/4/04	2/1/07	CWD, scrapie, BSE
Montana	4/25/05	4/1/08	TSEs *including* CWD, scrapie, BSE
North Dakota	3/4/04	1/21/07	CWD, scrapie, BSE
South Dakota	3/4/04	2/1/07	CWD, scrapie
Utah	3/4/04	2/1/07	CWD, scrapie
Wyoming	4/6/04	1/21/07	CWD, scrapie, BSE

Environ LpH® has three approved application uses for TSE contaminated workspaces:

a. Washable, hard, non-porous surfaces;
b. Lab instruments, sharps and sharp containers; and
c. Laboratory waste solutions.

Sodium hypochlorite and NaOH may be used in some laboratories for general decontamination of surfaces and should be clearly documented in the industrial waste survey submitted by the facility.

3. Discharge of Wash and/or Rinse Waters

The chemical formulations that are used for inactivation are corrosive. Subsequent to the chemical inactivation step, treated surfaces receive a final wash and/or rinse to remove residual chemicals. Chemicals used for inactivation and decontamination can be incompatible with the microorganisms that the POTWs rely on to provide treatment or the chemicals may pass through the POTW into receiving waters. The pollutants that may be present in the discharge are discussed in Section IV.

4. Discharge of Blood

One of EPA's objectives under the Clean Water Act is the recycling and beneficial reuse of biosolids. Biosolids may be a valuable nutrient supplement to clay or nutrient poor soils, and in Region 8 states, land application of biosolids is economically feasible because of the vast open space and arid climate.

The fate and transport of the CWD agent in the environment are largely unknown. It is plausible that CWD agents occurring in infected tissues (including blood) subsequently transferred to soil via land application of biosolids could serve as a source for future exposure to uninfected animals in the wild. However, the significance of this exposure pathway is not known at this time. Some evidence indicates that TSE agents can survive for extended periods of time in soil [3,4,5]. Uncertainty stems from incomplete knowledge in many arenas, including 1) the nature of interactions between the CWD agent and soil particles as compared to water; 2) the long-term fate and transport of the CWD agent in the environment (stability and breakdown); 3) appropriate analytical methods for detecting the CWD agent in environmental media; 4) the infective dose or threshold of exposure necessary to cause disease; and 5) the shape of the dose-response curve. Region 8 continues to evaluate all of the credible research as it becomes available.

It is generally accepted that blood ranks much lower in TSE agent load compared to brain, spinal column, and lymphoid tissue [6,7]. However, some experimental evidence indicates that TSE agents can be transmitted through blood. Blood transfusions from sheep experimentally infected with BSE or naturally infected with scrapie transmitted disease to disease-free sheep [8,9]. Leukocytes (white blood cells) from primates experimentally infected with BSE or Gerstmann-Straussler-Scheinker disease transmitted disease to other primates [10,11]. Two instances of transmission of vCJD in humans via transfusion of red blood cells have been reported (one case was manifested clinically and the second was identified at autopsy following death from an unrelated cause) [12,13].

Accordingly, laboratories processing carcasses of (and organs/tissues from) animals potentially contaminated with CWD should implement measures to minimize, to the greatest extent possible, the amount of untreated blood entering drains. POTWs should ensure that laboratories take appropriate steps to minimize the amount of blood exiting the lab via drains before accepting waste from such labs. Such practices may include, but are not limited to:

a. Installation of a double layer of screening over drains to trap large blood clots;

b. Implementation of protocols that restrict the amount of blood escaping the carcass during necropsy procedures; and

c. Implementation of process controls, such as limiting the volume of running water sometimes used during necropsy procedures to keep the floor clear of blood and debris.

C. Best Management Practices (BMPs)

It is important from a practical standpoint to minimize the amount of wastewater that is generated for disposal, whether in the initial tissue removal or final rinse. Inefficient practices can result in higher disposal costs for the discharger. It is strongly recommended that dischargers evaluate how to minimize the collection and treatment of significant quantities of rinse water.

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) Laboratory Safety and Waste Disposal Committee and Pathology Committees have developed BMPs for use by animal health laboratories for CWD, TME and scrapie diagnostic samples [(14)]. These BMPs offer guidance for disposal of contaminated waste from laboratory professionals. A number of the AAVLD recommendations are incorporated into this Strategy.

The following BMPs are provided to allow the POTW to evaluate what procedures may be implemented by a discharger to ensure that TSE contaminated materials are contained to the greatest extent that is feasible, adequate decontamination treatment is implemented and, treatment is implemented in the most effective manner to ensure minimal waste is generated. In many cases, the discharger will prevent solids from entering the sewer system, but may discharge waste water containing blood from potentially TSE infected animals. Section III.B.4. provides additional information on the discharge of blood that the POTW should review. EPA is not requiring the following BMPs. The appropriate BMPs will be determined by a POTW based upon its decision to conditionally allow or prohibit a specific discharge.

1. Use of disposable, absorbent, bench top materials and/or receptacles to prevent tissues from becoming a component of the wastewater discharge is recommended. Many laboratory supply houses sell rolls of bench top absorbent toweling (with plastic backing) that are used to cover the benches where dissection and tissue preparation occur.

2. Use of disposable clothing or coveralls. Laboratory clothing may be contaminated with some amount of blood or small tissue fragments, which may contain active TSE agents (see Section III, B. 4.). Detergents and hot water have not been demonstrated to be effective at inactivation of TSE agents. Disposable clothing may be useful for certain laboratory staff/procedures where laboratory clothing can become contaminated with blood or other tissues from TSE suspect animals.

3. Use of physical containment around work areas to minimize the area of floor cleanup. The laboratory or facility should evaluate the physical floor space where animal tissues are processed. If the floor is washed down, isolating or minimizing the area that requires washing is recommended. A POTW evaluation of discharges should be performed on-site. Where the discharger believes safety considerations prevent this approach, other practices may be implemented (see Section III.D.)

4. Use of disposable floor coverings. In areas where floors may be splattered with animal tissues, disposable floor coverings may be useful to avoid generating wastewater during the tissue removal step, and are recommended when practicable. POTW evaluation of discharge practices should be performed on-site during an inspection. Where the discharger believes safety considerations prevent this approach, other practices could be implemented (see Section III.D.)

5. Floor drains and other pathways of contaminated wastewater may be segregated or redirected to containment for further treatment and/or waste management. Plumbing changes may be required as a condition of discharge to the POTW.

6. Disposable or dedicated equipment, instruments and supplies should be used when possible when TSE suspect necropsies are performed.

7. Receptacles should be used to catch fluid wastes from necropsy tables and suspended decapitated carcasses. Absorbable materials may be used to capture liquids. However, use of these materials may increase the amount of solid waste that is generated for disposal.

8. Potentially contaminated formalin or other liquids should not be discharged, but should be incinerated or recycled with appropriate disposal of remaining solids, or chemically neutralized and disposed of in accordance with Federal, state and local regulations.

9. Microtomy wastes and formalin fixed tissues should be collected and properly disposed of; they should not be discharged.

10. Drains should be screened to trap tissue fragments and large blood clots to minimize the amount of potentially infectious material entering drains (see Plumbing Considerations in Section III.D.).

D. Plumbing Considerations

Several plumbing modifications or considerations may be undertaken at the facility. The major activities include installing screens over drains, installing a system designed to allow segregation of flows for chemical treatment if necessary, and/or controlling discharge options for sinks and other appliances. Materials used in these modifications should be non-porous and resistant to corrosion where needed.

To catch large solids and residues before contaminated material may leave the work area (to drain or sump), screening should be placed over the drain grates or openings. Screen material should have a maximum opening or hole-size of approximately one to two millimeters. This will still allow passage of smaller particles to the drain system. The discharger must ensure that voids or spaces on or around the drains which would allow solids to enter or bypass the screens are not present. The screening should be applied in two layers to assure that the integrity is not compromised during use. The discharger should perform a visual inspection of all screening on a daily basis and replace it as needed.

Note: Use of a galvanized metal screen over the drains may result in an unacceptable level of zinc in the discharge. Zinc is the primary metal in galvanizing solutions and acid etches zinc from the galvanized surface.

Many facilities have trench type drain systems with grates over the top. Other facilities have a central drain or several dispersed floor drains. Where a facility opts to generate wastewater in a pre-inactivation step rather than a dry process (mechanical or disposable floor covering), a removable plug, valve or other adequate equipment (e.g. containment) may be installed in drains to minimize or prevent discharge of untreated TSE contaminated tissues and residues to the sewerage system. This may also prevent inadvertent or accidental spills being discharged during the normal working day when processing animals and tissues. Treatment and discharge requirements of the wash and/or rinse water would be defined by the POTW permit.

To prevent accumulation of liquids on the floor prior to the inactivation step, the discharger may install a plumbing system that allows segregation of waste water away from the drain leading directly to the sewer system. A common method for capturing floor and surface wash down material is to use a sump pump that can send the accumulated solids and water to temporary storage where additional treatment can occur.

Sinks are used for a variety of purposes in the laboratory, the most common of which is rinsing of tools and equipment. TSE contaminated solids and tissues may be washed down the sink during this wash if adequate precautions are not taken. Some labs will also use sinks as an Environ LpH® basin for soaking tools and equipment. Direct discharge to the POTW sewer system of the concentrated Environ LpH® solution from the sink, as well as chlorine or sodium hydroxide, is not acceptable unless authorized by the POTW. The POTW must ensure that the discharge does not violate a Pretreatment Standard or Requirement.

Note: The use of sinks and toilet facilities for general domestic-only human waste are acceptable for direct discharge to the sewer system unless otherwise prohibited by the POTW.

IV. Chemical Specific Pollutants of Concern

Chemical inactivation of prions on laboratory surfaces, medical instruments and tools is achievable by the use of Environ LpH® (EPA Registration Number 1043-118). The use of sodium hypochlorite and/or sodium hydroxide as a treatment for prions has been reported from a number of sources [2,15-22].

Note: While only Environ LpH® is currently approved by EPA for this use by laboratories in the Region 8 states of Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming, the Strategy provides information on sodium hypochlorite and sodium hydroxide in anticipation of potential future approvals, and because laboratories currently may use these compounds for general decontamination.

A. Alkaline Hydrolysis Effluents [21]

Though there may be variations, alkaline hydrolysis involves the use of a concentrated alkaline solution (1 molar sodium or potassium hydroxide) along with elevated temperatures (150ºC) and pressures (approximately 5 bars) for a period of approximately 6 hours that ensures tissues and proteins (including CWD prions) are hydrolyzed or digested. The vessel in which this process occurs is best described as a very large stainless steel pressure cooker. The unit is generally computer controlled and may be

operated at one, two, or three cycles per day. The loading capacity for these units varies. However, various units are available that can handle 80 to 7000 lbs per cycle. The discharge from this process produces a very dense “soup” that contains physical and chemical constituents that POTWs will have to evaluate. The digestion and disposal of animal tissue from other causes of sickness (e.g. mercury or selenium poisoning) may require that the discharger notify and test the effluent prior to discharge to the POTW. Pretreatment regulations require the discharger to coordinate with the local government whenever discharge to a POTW is desired.

pH – The use of sodium hydroxide (NaOH) or potassium hydroxide (KOH) makes pH an immediate concern. Some POTWs have an upper limit for pH. Where a POTW does not have an upper pH limit, a limit of 12.5 is generally applied. Wastewater with a pH greater than 12.5 is a corrosive hazardous waste as defined at 40 CFR Section 261.22. If a facility discharges wastes with a pH>12.5, significant Federal reporting requirements are required as specified at 40 CFR Section 403.12(p). In addition, these discharges shall be made in compliance with POTW pretreatment standards and requirements.

BOD – Biochemical Oxygen Demand. This can be very high (>80,000 mg/L or approximately 1600 lbs per load for the largest of the alkaline hydrolysis units). This could be of concern to a smaller POTW or a POTW with limited available capacity.

Ammonia and TKN (Total Kjeldahl Nitrogen) - May be significant. The concentration is estimated by the manufacturer to be around 12,300 mg/L combined (251 lbs) per load for the largest of the alkaline hydrolysis units. The POTW may have to evaluate its capacity depending on the size of the unit installed.

Fluidity - The material that leaves the alkaline hydrolysis unit has a very thick consistency. Though the material leaves the unit at a fairly high temperature, as it cools the material becomes very viscous and may quasi-solidify. While many POTWs may have larger sewer lines where the material can mix to minimize potential sewer obstruction, discharges made to smaller service lines could result in overflows.

Metals - Some chemical reagents manufactured by raw materials at chlor-alkali plants (e.g. NaOH, chlorine products, caustic soda) should be evaluated for potential mercury contamination.

No other pollutants of concern have been identified as a significant issue for POTWs. It is expected that as these systems commence discharging to POTWs, additional monitoring will be performed by the POTW or by the facility and reported to the POTW which may result in identification of additional pollutants of concern.

B. Environ LpH®

Environ LpH® is composed of glycolic acid, an alcohol, a glycol and three phenols (see Attachment A). The formulation is that cited in studies [4,5,6] and is the formulation approved by EPA for use. The following is a list of ingredients (and see Attachment A).

Component	CAS No.	% by Weight	mg/L*
o-benzyl-p-chlorophenol	120-32-1	6.4	64,000
p-tertiary-amylphenol	80-46-6	3.0	30,000
o-phenyl phenol	90-43-7	0.5	5,000
Hexylene glycol	107-41-5	4	40,000
Glycolic acid	79-14-1	12.6	126,000
Isopropanol	67-63-0	8	80,000

* These are estimated concentrations. Actual concentrations will vary due to the specific gravity.

Aquatic (and other) Toxicity Information (selected data from EPA's Ecotox Database) for Environ LpH® components

Component	Algae LC_{50} mg/L	Insect LC_{50} mg/L	Fish LC_{50} mg/L	Other mg/L
o-benzyl-p-chlorophenol		0.46-0.76	0.2-1.2	Birds: >2,510
p-tertiary-amylphenol			0.063-3.34	Shrimp: 1.7
o-phenyl phenol	1-5	0.710-3.17	2.74-646	
Hexylene glycol – OSHA and ACGIH: 25ppm		2,400-4,000	5-11,000	Sea Urchin 7,266-13,555
Glycolic acid				Protozoan: 400-1,220
Isopropanol	680	5,102	7,020	Protozoan: 754-7,462

The toxicity data listed above can be used to evaluate the individual components of Environ LpH® when setting local limits. The algae, insect and protozoan data may be used to protect the POTW from interference, whereas the fish data may be used to model the discharge to the POTW's receiving water.

Where a laboratory is using Environ LpH® as a microbial disinfectant, the suggested effective dose for microbial disinfection is one (1) ounce of stock solution concentrate per gallon of water. This is for rapid, acute disinfection of surfaces and instruments against bacteria and viruses. For CWD prion inactivation, laboratories will apply a five to nine percent (5-9%) solution (or 7-12 oz per gallon water) for a duration of at least 30 minutes or a 0.9% solution (1.5 oz per gallon water) applied for 16 hours (see Attachment B for an example use statement from Steris). An important note is that this product is approved not only for surface treatment, but also for immersion of lab instruments and as an additive to chemical solutions (e.g. formalin) as an inactivating agent. The additional volumes and associated waste chemicals should be evaluated by the POTW.

The actual concentration of Environ LpH® discharge to the POTW may not be accurately determined without the discharger collecting and analyzing the wastewater prior to discharge. The discharger should evaluate the representative concentration of LpH that is being discharged down the drain for the POTW. The POTW may request the discharger to determine the highest concentration of Environ LpH® that is discharged since the formulation acts as an antimicrobial agent.

The pH of concentrated Environ LpH® is 2.2 to 2.6 Standard Units (SU). The pH of a 1% solution is approximately 3.0 SU and the pH of a 10% solution is 2.6 SU[23]. The pH values are well below the Federal discharge limit of 5 standard units (some POTWs may require a higher minimum pH). POTWs will generally require monitoring for pH by the facility discharging wastewater. If the wastewater pH does not meet specific pH limits, the discharger will be required to install treatment as necessary to meet standards. All pH tests must be performed according to methods specified in 40 CFR Part 136. POTWs should carefully evaluate storage areas to make sure that Environ LpH® is not stored near an unprotected drain in case of a spill.

One component of Environ LpH®, p-tertiary-amylphenol, may be classified as an alkylphenol (nonylphenol). EPA is currently evaluating nonylphenols for a national water quality criterion because of their significant toxicity to aquatic life. Nonylphenols are being identified as possible contributors to Interference/Pass Through at POTWs [24,25].

C. Chlorine (as a solution of sodium hypochlorite)

Disinfectants containing sodium hypochlorite (e.g. bleach) may be used for microbes at some labs. The concentration of chlorine reported for TSE inactivation ranges from 20,000-60,000 mg/L for one hour [2,17,20,22]. These solutions are generally prepared immediately prior to use because of the instability of the active ingredient.

POTWs and public water supplies use chlorine as a wide spectrum disinfectant. Chlorine is very toxic to aquatic life and using it requires POTWs to dechlorinate their effluents prior to discharge to receiving waters. The concentrations necessary to cause acute and chronic toxicity to aquatic life are 0.019 and 0.011 mg/L, respectively. The concentration of free chlorine used by labs for decontamination can be orders of magnitude greater than the acute and chronic criteria. This high toxicity requires the POTW to carefully evaluate the acceptable concentration of chlorine in a non-domestic discharge to the POTW.

The concentration of free chlorine will be reduced significantly during surface treatment in the facility. Further, when a discharge to a POTW occurs, contact with other organics will reduce the free chlorine. POTWs and dischargers need to monitor chlorine to ascertain acceptable levels and avoid pass through or interference. The critical issue for the POTW appears to be ensuring the free chlorine level and the total residual chlorine levels are very low or not detectable leaving the primary clarifier of the POTW. Region 8 suggests that contributions of chlorine by dischargers to the POTW not exceed a concentration that would cause a maximum of 0.1 mg/L free chlorine to be exceeded at the headworks. The POTW needs to evaluate the acceptable level of total residual chlorine, if any, it is willing to allow at the headworks. A number of POTWs have responded that they accept chlorine contaminated wastewaters from dischargers, but in no case will they allow those discharges to result in a measurable influent total residual chlorine level. Other POTWs may allow a discharge(s) to cause the influent to have a measurable amount of total residual chlorine. Should these POTWs allow any significant chlorine at the headworks, they should carefully monitor the influent and effluent from primary clarification to ensure that biological activity is not adversely impacted.

Dischargers may be required to contain and de-chlorinate their wastewater prior to discharge to the POTW where the POTW determines this treatment is required.

Note: The discharger should specifically remove or secure cleaners that contain ammonia as an ingredient. Mixing of ammonia cleaners with chlorine can result in the production of hazardous fumes that can cause injury or death. Hypochlorite is also incompatible with strong acids, oxidizable materials, nickel, copper, tin, manganese, iron, urea and formalin.

D. Sodium Hydroxide

Sodium hydroxide (NaOH) is a disinfectant that may be used by some labs. For surface treatment, use of a 1M NaOH solution has been reported for inactivation of TSE agents [2,17,18,19], though a 2 M NaOH solution has been recommended to be more effective [18]. There are many grades of NaOH and the formulation used should be reviewed by the POTW. The only pollutant of concern that has been identified in some NaOH reagents is mercury, though it does not appear to be common. The POTW should evaluate the specific NaOH used to eliminate mercury as a pollutant of concern. The use of NaOH may result in high pH in discharges that violate POTWs pH local limits. If the discharge requires treatment, the most commonly employed would be flow equalization and pH adjustment.

E. Incinerator Scrubber Water

POTWs have not reported the discharge of scrubber waste water from a TSE incinerator to a POTW. If discharges are identified in the future, EPA will make any data on the quality of the waste water available.

V. Pretreatment Program Requirements and Local Limits

Chemical specific Local Limits shall be developed in accordance with the latest revision of the EPA Region 8 Technically-based Local Limits Strategy [26] or other approved state procedures. As with other pollutants that may be unique to a specific discharge, the POTW has two options for developing and implementing local limits. In the first option, the POTW develops a local limit for a specific pollutant and submits this to the Approval Authority for approval. In the second option, the POTW develops a local limit for the pollutant and inserts this local limit directly in the permit or control mechanism for that discharger. This permit or control mechanism must be public noticed by the POTW for at least 30 days in a newspaper of general circulation and provided to the Approval Authority for review, comment and approval. Since, there is no direct analytical method available for quantifying the concentration of TSE agents in wastewater or biosolids, the POTW will use BMPs and discharge controls to address discharges to the POTW.

Under the Pretreatment Program, no non-domestic discharger shall discharge any material that causes a violation of the general or specific prohibitions specified in 40 CFR Section 403.5, Categorical Standards or any specific effluent limits established by the POTW. The laboratory will generally have a permit or authorization to discharge from the POTW. The permit will authorize discharge, limit pollutants, establish BMPs, require monitoring, specify reporting requirements, and provide specific notice of the discharger's responsibilities. Limits will be established by the POTW on a case-by-case basis, taking into account but not limited to, such considerations as flow from the discharger, concentration of pollutants in the

discharge, pollutant loadings from other users, impact to the treatment works and sewerage system, pass through of pollutants, threat to workers, and contamination of biosolids. EPA Region 8 has already established general procedures for POTWs to use when developing local limits and will assist a POTW as necessary.

It is the responsibility of the discharger to monitor its discharge and submit all monitoring data to the permitting authority. The discharger should carefully review the test results provided by the commercial lab or on-site staff. The discharger will be required to sign and submit a monitoring report to the permitting authority, usually on a monthly or quarterly basis. The discharger is responsible for identifying all non-compliant test results or other violations (40 CFR Section 403.12(g)). The pretreatment program requires that these be reported to the permitting authority within 24 hours of becoming aware of the violations (usually receipt of the results) and retest within 30 days for any parameter that is non-complying.

Some laboratories may discharge to septic tanks and leach fields. Overtime, septic tanks may accumulate or concentrate high quantities of chemicals that are discharged down the drain. The POTW must be very cautious in accepting these wastes without a full characterization of the waste. The POTW should verify that all manifests for waste being brought to the POTW have been completed by the haulers. EPA recommends that a chemical analysis be completed for those pollutants regulated by the POTW for the chemicals identified in the industrial waste survey by laboratories working with TSE agents.

VI. References

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Note: For other references see FAQ and Response to Comments section below.

ATTACHMENT A

Environ LpH® MSDS

STERIS

SAFETY DATA SHEET

1. Identification of the Substance and Company

Environ® LpH®

Product No. 6405
MSDS No. 6405

NFPA 704 HAZARD RATING:
HEALTH: 3
FIRE: 1
REACTIVITY: 0

Prepared by: M. Ebers
Date Created: August 27, 2002 **Date Revised: February 4, 2005**

STERIS Corporation, P. O. Box 147, St. Louis, MO 63166, US
Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC)
Telephone Number for Information: 1-800-548-4873 (Customer Service-Healthcare Products)

STERIS Limited, STERIS House, Jays Close, Viables, Basingstoke, Hampshire, RG22 4AX, UK
Emergency Phone No: +44 (0) 1895 622639
Product/Technical Information Phone No: +44 (0) 1256 840400

2. Composition/Information on Ingredients

Hazardous Component(s)	EEC No.	CAS No.	% By Wt.	Symbol	R Phrases
o-benzyl-p-chlorophenol	204-385-8	120-32-1	6.4	[C]	[34]
p-tertiary-amylphenol	201-280-9	80-46-6	3.0	[C/X_n]	[34, 22]
o-phenyl phenol	201-993-5	90-43-7	0.5	X_i; N	36, 37, 38, 50
Hexylene glycol	203-489-0	107-41-5	4.0	X_i	36, 38
Glycolic acid (Hydroxyacetic acid)	201-80-5	79-14-1	12.6	[C]	[34]
Isopropanol	200-661-7	67-63-0	8.0	F; X_i	11, 36, 67

3. Hazards Identification: Corrosive to eyes and skin. Very toxic to aquatic organisms.

4. First Aid Measures
Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation develops, contact a physician.
Skin Contact: Immediately flush skin with plenty of water for at least 15 minutes. Contact a physician if irritation persists.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and call a physician.
Ingestion: If swallowed, Do NOT induce vomiting. Give large quantities of water. Call a physician immediately. Never give anything by mouth to an unconscious person.

5. Fire-Fighting Measures
Flash Point: 123°F (50°C) PMCC
Special Hazards: Product is combustible. Use media appropriate for the primary source of fire.
Extinguishing Media: Suitable for surrounding fire: water, CO_2, foam, dry chemical.
Special Fire Fighting Procedures: Use self-contained breathing apparatus.

6. Accidental Release Measures:
Ensure suitable personal protection during removal of spillages. Spills should be contained and may be cautiously neutralized with sodium bicarbonate, or absorbed on appropriate material and placed in a container for disposal. Flush spill site with large quantities of water to a sanitary sewer. Washings should be prevented from entering surface water/storm drains. Local regulations should be observed.

7. Handling and Storage
7.1 Handling
Product will withstand an occasional accidental freezing. It must be thoroughly thawed and agitated (roll drum) before being used.
7.2 Storage
Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

8. Exposure Control/Personal Protection
8.1 Occupational Exposure Limits
Hexylene glycol: ACGIH TLV and OSHA PEL = 25 ppm;
Isopropanol: ACGIH TLV = 200 ppm; OSHA PEL, UK HSE LTEL = 400 ppm; ACGIH STEL, UK HSE STEL = 500 ppm, MAK = 200 ppm
8.2 Personal Protection
Respirator Protection: Required when exposure limits exceeded. **Eye Protection:** Safety glasses or goggles..
Protective Gloves: Rubber **Other Protective Clothing and Equipment:** NA
Ventilation: Adequate ventilation to maintain air concentrations below established limits.

9. Physical and Chemical Properties
Solubility in Water: Complete **Specific Gravity:** Approximately 1.05 g/ml
Appearance/Odor: Clear, amber liquid/ phenolic odor **pH:** Approximately 2.2 – 2.6

10. Stability and Reactivity
Stability: Stable **Hazardous Polymerization:** Will not occur.
Incompatible Materials: None known. **Hazardous Decomposition or Byproducts:** None known.
Conditions to Avoid: None known.

11. Toxicological Information
11.1 Acute (Primary Routes of Exposure)
Eyes: Product may be corrosive to the eyes. .
Skin: Product may be corrosive to the skin. Dermal LD_{50} (rabbit) > 5,000 mg/kg. Dermal sensitizer in guinea pigs.
Inhalation: Product is not expected to be toxic by inhalation. May be irritating.
Ingestion: Product is not expected to be toxic through ingestion. Oral LD_{50} (rat) > 5,000 mg/kg.
11.2 Long Term Exposure : None known.
Carcinogenicity: IARC, NTP and OSHA do not list this product or its ingredients as carcinogens. 2-phenylphenol produced urinary bladder tumors in male rats and liver tumors in male mice when fed exaggerated doses.

12. Ecological Information: None available

13. Disposal Considerations: Do not contaminate ponds, waterways, or ditches with chemical or used containers. Empty containers should be rinsed thoroughly and discarded in an appropriate waste container. [Containers may be offered for reconditioning/recycling.] Empty containers should not be used for other purposes. Unused material may be a hazardous waste due to its low pH and subsequent corrosivity. Disposal of wanted product should be done in accordance with local, state or national legislation. Product may be flushed to a sanitary sewer with copious amounts of water, if in accordance with state, local and federal regulations. For additional guidance, contact the State Water Board or the Regional Office of the EPA.

14. Transport Information
Ground/ Sea/ Air: Disinfectant, Liquid, Corrosive N.O.S. (o-phenylphenol and o-benzyl-p-chlorophenol) 8, UN 1903, PG II

15. Regulatory Information
EEC Classification: IRRITANT/DANGEROUS FOR THE ENVIRONMENT
Hazard Symbol: C/N
Risk Phrases: R34: Causes burns. R43: May cause sensitization by skin contact. R50: Very toxic to aquatic organisms.
R67: Vapours may cause drowsiness and dizziness.
Safety Phrases: S2: Keep out of reach of children. S16: Keep away from sources of ignition – No smoking. S24/25: Avoid contact with skin and eyes. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/S37/39: Wear suitable protective clothing, gloves and eye/face protection. S45: In case of accident or if you feel unwell seek medical advice immediately (show label when possible). S61: Avoid release to the environment. Refer to special instructions/Safety data sheet.
EPA Registration Number: 1043-118
US EPA Regulations: o-phenylpehnol subject to reporting under Section 313 of Title III (SARA) and 40 CFR 372.
USA State Regulations: May contain trace levels of formaldehyde. Contains o-phenylphenol.

16. Other Information: The information on this sheet is not a specification and does not guarantee specific properties. The information is intended to provide general knowledge as to health and safety based upon our knowledge of the handling, storage and use of the product. It is not applicable to unusual or non-standard uses of the product or where instructions or recommendations are not followed.

NA - Not Applicable ND - Not Determined

Attachment B

Steris Environ LpH® Section 18 Emergency Exemption Use Directions (Example given is for North Dakota).

STERIS

SECTION 18
EMERGENCY EXEMPTION USE DIRECTIONS
For Sale and Use in North Dakota for Use on Hard Surfaces for Treatment of Potential Prion Contamination Associated with deer, elk, sheep, and beef tissues.

STERIS Environ LpH®

All Applicable directions restrictions and precautions on the EPA-registered product label for Environ LpH (EPA Reg. No. 1043-118) must be followed.

These directions for use must be in the possession of the user at the time of application.

Any adverse effects resulting from the use of Environ LpH under this emergency exemption must be immediately reported to the North Dakota Department of Agriculture.

Effective Dates: *March 4, 2004* thru *January 21, 2007*

EPA File Symbol: 03-ND-*22*

Directions for Use:
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

1. Sites to be Treated: Commercial and government laboratories , including testing, diagnostic, research, and necropsy laboratories and other related facilities that handle deer, elk, sheep, and beef tissues and wastes that are potentially contaminated by prions, the causative agents for the following transmissible spongiform encephalopathies (TSEs): chronic wasting disease (CWD), scrapie and bovine spongiform encephalopathy (BSE).

2. Environ LpH may be used on washable, hard, non-porous surfaces (such as floors, tables, equipment, and counters), items (such as non-disposable instruments, sharps, and sharp containers), and/or laboratory waste solutions (such as formalin or other liquids). Thoroughly mix the treatment solution until uniform. Remove gross filth mechanically before treatment begins. Apply a 5-9% concentration of the Environ LpH diluted in water (7-12 ounces of product to 1 gallon of water) to washable, hard, non-porous surfaces or items by mop, cloth, sponge, brush, squirt bottle, low volume coarse spray applicator, or immersion and maintain contact for at least 30 minutes. Re-treat as necessary to keep wet throughout the 30 minute time period. Following the contact time, surfaces or items may be rinsed with water and allowed to air dry. Items may also be soaked in a 0.9% concentration of the product (1.5 oz of product per gallon of water) for at least 16 hours. For laboratory waste solutions, add Environ LpH to create a final

concentration of 5-9% and allow a treatment period of at least 30 minutes or add Environ LpH to create a final concentration of 0.9% and allow a treatment period of at least 16 hours. Applications may be made on an as needed basis by qualified personnel in commercial and government laboratories that handle potentially CWD and/or scrapie contaminated animal tissues.

3. Maximum Number of Applications: Not limited