Versa-Clean™
Pharmaceutical Production Multi-Purpose Cleaner

A White Paper
Fact Sheet

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Introduction

Versa-Clean is a safe and effective aqueous cleaner combining the cleaning actions of both anionic and non-ionic surfactants to emulsify, lift, disperse and suspend a broad spectrum of soils and contaminants.

From delicate labware to full scale production equipment in pharmaceutical manufacturing and where surfaces must be totally free of inhibitory residues that could interfere with analysis, tissue culture, manufacturing and critical procedures.

Standard Methods

Can be used manually or with standard (CIP) clean-in-place and (COP) clean-out-of-place methods in industries such as, pharmaceutical, biomedical, chemical, environmental, food, water and waste-water testing to name a few. Versa-Clean Multi-Purpose is concentrated and can be diluted with up to 60 parts water depending on the specific requirement, eliminating the need for multiple product validations.

NELAC Inhibitory Residue Test

The NELAC Institute (National Environmental Laboratory Accreditation Conference) has combined with INELA (Institute for National Environmental Laboratory Accreditation) into one organization to form TNI (The NELAC Institute) dedicated to the vision that all entities generating environmental data in the United States be accredited to a national standard (http://www.epa.gov/NELAC).

In order to comply with TNI Standards, a laboratory has to have a documented procedure for washing labware. Detergents designed for laboratory use must be used. Labware that is washed and reused shall be tested for possible presence of residues which inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually and each time the lab changes the lot of detergent or washing procedures (NELAC Standard, 2003).
Versa-Clean is third party, lot specific tested using Standard Methods for the Examination of Water and Wastewater 21st Ed., method 9020B-4a-2. The 2003 NELAC Standard is EPA (US Environmental Protection Agency) approved as documented in EPA/600/R-04/003. An example of the test results is shown above.
No Hazardous Ingredients

Versa-Clean’s unique formulation is exempt of the many undesirable components commonly found in critical cleaning agents, such as: alcohol, ammonia, chlorine, caustic, fragrance, glycol ether solvents, NTA, silicates, solvents, sulfates, volatila organic compunds or ozone depleting substances.

More specifically, Versa-Clean does not contain any APE’s (alkyphenol ethoxylates) or NPE’s (nonylphenol ethoxylates) and it does not contain phosphates.

Versa-Clean also does not contain any component reportable under Section 313 of the EPCRA nor section 6607 of the PPA (Pollution Prevention Act), nor does it contain any hazardous air pollutants under the CAA (Clean Air Act) or any Class 1 or Class 2 ozone depletors or any other product listed as either a “Hazardous Substance”, a “Priority Pollutant” or a “Toxic Pollutant” under the CWA (Clean Water Act).

There are numerous products currently being used in the pharmaceutical production industry that will be subject to eventual formulation changes as a result of their alkylphenol or nonylphenol ethoxylate content and/or their phosphate content, requiring updated validation of SOP’s.

No NPE’s, APE’s

NPEs are widely used in cleaning agent formulations commonly used for critical cleaning. NPEs are part of a broader category of non-ionic surfactants known as APEs.

NPEs, though less toxic than NP, are highly toxic to aquatic organisms and in the environment degrade to NP which is persistent in the aquatic environment, moderately bio accumulative and extremely toxic to aquatic organisms. NP has also been detected in human breast milk, blood and urine and is associated with reproductive and developmental effects in rodents (EPA, 2010).

Internationally, Canada and the EU have acted to regulate NP and NPEs. The UNEP (United Nations Environment Program) has identified NP as a chemical of global concern in its Regionally-based Assessment of Persistent Toxic Substances (UNEP, 2003). Under the CEPA (Canadian Environmental Protection Act, 1999), the federal government has developed preventive or control measures for NPEs.

The EPA intends to initiate actions to protect the environment from exposure to NP and NPEs due to manufacture (including import) use, or disposal of commercial NP and NPEs. (EPA, 2010).

The EPA believes that the following actions, among others, would be warranted:

(1) Supporting & encouraging the voluntary phase out of the use of NPEs in industrial detergents;

(2) A TSCA (Toxic Substances Control Act of 1976) SNUR (significant new use rule) and a test rule for NP and NPEs;

(3) To add NP and NPEs to the list of chemicals under TSCA Section 5(b)(4) that present an unreasonable risk of injury to the environment;

(4) Initiating rulemaking (2011) to add NP and NPEs to the TRI (Toxic Release Inventory) list.
Phosphate Free

Phosphates have been widely used as all-purpose components in commercial cleaning agents to contribute to product detergency by providing and controlling alkalinity.

Phosphates carry into waste systems and are hard to break down by ordinary wastewater treatment facilities. As they carry into waterways, they increase algae growth which in turn causes eutrophication, a condition where the water becomes depleted of oxygen. This kills existing plants and animals that live in the water source.

In the 1960's and early 1970's, consumer agencies began calling for their ban. The detergent industry continues to use phosphates in their products on a large scale, but as of July 2010 individual states can voluntarily regulate their use in commercial products.

States that have adopted this ban or are increasing their regulation of the sale of phosphate detergents include Illinois, Indiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, New Hampshire, Ohio, Oregon, Pennsylvania, Utah, Vermont, Virginia, Washington and Wisconsin.

Versa-Clean’s unique formulation is phosphate free.

Readily Biodegradable

Until recently, there were few legal standards regarding marketing claims surrounding the use of the term 'biodegradable'. In 2007, the state of California passed regulation banning companies from claiming their products are biodegradable without proper scientific certification from a third-party laboratory. The OECD (Organisation for Economic Co-Operation & Development) was founded in 1960 by 18 European countries, the US and Canada to create an organisation dedicated to global development. (http://www.OECD.org/home).

The OECD has established guidelines for testing of chemicals. Test 301d is used to determine whether a solution is readily biodegradable (whether the test item achieves 60% or more degradation in 28 days). Versa-Clean was tested using the readily biodegradability closed bottle test OECD method #301D, 1992.
As shown on the graph below, Versa-Clean achieved a degradation of more than 60% in 28 days. Based on the best fit curve (polynomial), the test item achieved 66.1% degradation in 10 days and 79.0% degradation after 14 days (Stantec Consulting Ltd., 2007).

### RESULTS

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<th>4</th>
<th>7</th>
<th>11</th>
<th>14</th>
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<td>61.3</td>
<td>73.8</td>
<td>75.0</td>
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**Test Results:**

The test item achieved ≥60% degradation in 28 days.

Based on the best fit curve (R² = 0.9099), the test item achieved 66.1% degradation 10 days after achieving 10% biodegradation (10 day window).

Based on the best fit curve (R² = 0.9099), the test item achieved 79.0% degradation 14 days after achieving 10% biodegradation (14 day window).

* polynomial = best fit curve for test substance biodegradation data

$$y = -0.1723x^2 + 7.3463x + 9.8068$$  
$$R^2 = 0.9099$$

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**Approved by:** Project Manager
**TSCA Requirements**

The TSCA (Toxic Substances Control Act of 1976) provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures (http://www.epa.gov/lawsregs/laws/tsca.html). It is a law implemented by the OCSP (Office of Chemical Safety and Pollution Prevention) (http://www.epa.gov/aboutepa/ocspp.html).

The EPCRA (Emergency Planning and Community Right-To-Know Act) or the Community Right-To-Know Law, is also known as Title III of SARA (Superfund Amendments and Reauthorization Act). It provides specific plans to prepare for, prevent and respond to the release of over 600 chemicals currently listed in TSCA’s Toxic Release Inventory (TRI). Versa-Clean does not contain any ingredients on the TRI.

**pH and Disposal**

The term RCRA (Resource Conservation and Recovery Act) is often used to refer to law, regulations and EPA policy and guidance. It describes the waste management program mandated by Congress that gave EPA the authority to develop the RCRA program.

Versa-Clean does not contain any components that are listed as banned material from land disposal according to RCRA.

pH is a measure of the acidity or basicity (alkalinity) of an aqueous solution. Pure water is said to be neutral with a pH close to 7.0 at 25 °C (77 °F). Solutions with a pH less than 7 are acidic and solutions with a pH greater than 7 are basic or alkaline.
**Non Corrosive**

The EPA uses two criteria to identify liquid and aqueous corrosive hazardous wastes (40 CFR, part 261.22 Code of Federal Regulations):

(1) Aqueous wastes with a pH greater than or equal to 12.5 or less than or equal to 2;

(2) A liquid waste may also be corrosive if it has the ability to corrode metal containers, such as storage tanks, drums, and barrels.

Versa-Clean is non-corrosive with a pH of 9.75-10 (undiluted), contains corrosion inhibitors and can be disposed of in accordance with all applicable local, state and federal laws.

**Quality Assurance**

Fisherbrand Versa-Clean is manufactured using sustainable, low waste and low energy processes in an audited, modern plant, using state of the art, precision production equipment.

From material reception, to strictly monitored processes, documented procedural controls for complete traceability are maintained at every level of manufacturing.

Available manufacturing documentation includes: Lot specific certificates of analysis, inhibitory residue tests, trace analysis as well as material safety data sheets, technical bulletins and white papers.

**References**

- Activation Laboratories, Inhibitory Residue Test Report W/O A12-00234, Lot # 5698 Ancaster, ON, Canada.


- Stantec Consulting Ltd., 2007, Biodegradation Test Report, W/O 211506, Sample No. 18797, Guelph, ON, Canada.


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