



PeelVue+™ Sterilization Pouches: Toxicity and Hazardous Waste

PeelVue+ Sterilization pouches do not meet the definition of a HAZARDOUS WASTE as defined by 40 CFR 261.241 when tested using the Toxicity Characteristic Leaching Procedure, EPA Publication SW-846. The product does not contain Lead (>5mg/L or 5ppm) other listed chemicals above statutory limits. 1Title 40: Protection of Environment, PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE, Subpart C—Characteristics of Hazardous Waste, § 261.24 Toxicity characteristic.

Sincerely,

Dux Dental B.V.

A handwritten signature in blue ink, appearing to be "J. Doorman", written over a horizontal line.

J. Doorman
Managing Director



LA Testing

10772 Noel St., Los Alamitos, CA 90720

Phone: (714) 828-4999 Fax: (714) 828-4944 Email: losalamitoslab@latesting.com

Attn: **Paul Wittrock**

**600 E. Hueneme Road
Oxnard, CA 93033**

Fax: Phone:
Project: **Dux Dental 600 E. Hueneme Road, Oxnard, CA 93033**

Customer ID: 32MISC-ACC
Customer PO:
Received: 02/01/08 9:25 AM
LA Testing Order: 330800913
LA Testing Proj:
Report Date: 5/29/2008

Toxicity Characteristic Leaching Procedure (SW846, 1311/7420)

Lab ID:	Analyzed	RDL	Lead Concentration	Notes
0002		0.4 mg/L	0.4 mg/L	
Client Sample Sheet of Paper, Peel Vue Pouch				Collected: 1/29/2008

Michael Chapman, Laboratory Manager
or other approved signatory

This report relates only to those items tested. Sample received in acceptable condition unless otherwise noted.



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Soluble Threshold Limit Concentration

<i>Lab ID:</i>	<i>Analyzed</i>	<i>RDL</i>	<i>Lead Concentration</i>	<i>Notes</i>
0003		0.4 mg/L	<0.4 mg/L	
Client Sample Sheet of Paper, Peel Vue Pouch				Collected: 1/29/2008

Michael Chapman, Laboratory Manager
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Total Threshold Limit Concentration

<i>Lab ID:</i>	<i>Analyzed</i>	<i>RDL</i>	<i>Lead Concentration</i>	<i>Notes</i>
0002		40 ppm	<40 ppm	
Client Sample	Sheet of Paper, Peel Vue Pouch			Collected: 1/29/2008

Michael Chapman, Laboratory Manager
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Test Methods

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SW-846 Manual

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- [SW-846 ON-LINE](#)
- [SW-846 Federal Register Notices](#)
- [New Methods](#)
- [Methods Innovation Rule \(MIR\)](#)
- [Waste Sampling Draft Technical Guidance](#)

What is SW-846?

The EPA publication SW-846, entitled *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*, is OSW's official compendium of analytical and sampling methods that have been evaluated and approved for use in complying with the RCRA regulations. SW-846 functions primarily as a guidance document setting forth acceptable, although not required, methods for the regulated and regulatory communities to use in responding to RCRA-related sampling and analysis requirements.



SW-846 is a multi-volume document that changes over time as new information and data are developed. It has been issued by EPA since 1980 and is currently in its third edition. Advances in analytical instrumentation and techniques are continually reviewed by OSW and incorporated into periodic updates to SW-846 to support changes in the regulatory program and to improve method performance and cost effectiveness. To date, EPA has finalized Updates I, II, IIA, IIB, III, IIIA, IIIB, IVA and IVB to the SW-846 manual, and the updated and fully integrated manual contains approximately 3500 pages.

Paper Copy of SW-846

An official printed copy of SW-846 and most of its updates can be purchased the National Technical Information Service (NTIS). Since SW-846 is available on-line the, U.S. Government Printing Office (GPO) subscription is no longer available.

National Technical Information Service

NTIS offers both copies of the current, fully integrated manual and individual copies of most updates and the basic manual (Third Edition before any updates). These documents can be obtained by contacting:

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ABSTRACT

Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846) provides test procedures and guidance which are recommended for use in conducting the evaluations and measurements needed to comply with the Resource Conservation and Recovery Act (RCRA), Public Law 94-580, as amended. These methods are approved by the U.S. Environmental Protection Agency for obtaining data to satisfy the requirements of 40 CFR Parts 122 through 270 promulgated under RCRA, as amended. This manual presents the state-of-the-art in routine analytical tested adapted for the RCRA program. It contains procedures for field and laboratory quality control, sampling, determining hazardous constituents in wastes, determining the hazardous characteristics of wastes (toxicity, ignitability, reactivity, and corrosivity), and for determining physical properties of wastes. It also contains guidance on how to select appropriate methods.

Several of the hazardous waste regulations under Subtitle C of RCRA require that specific testing methods described in SW-846 be employed for certain applications. Refer to 40 *Code of Federal Regulations* (CFR), Parts 260 through 270, for those specific requirements. Any reliable analytical method may be used to meet other requirements under Subtitle C of RCRA.

METHOD 1311

TOXICITY CHARACTERISTIC LEACHING PROCEDURE

1.0 SCOPE AND APPLICATION

1.1 The TCLP is designed to determine the mobility of both organic and inorganic analytes present in liquid, solid, and multiphasic wastes.

1.2 If a total analysis of the waste demonstrates that individual analytes are not present in the waste, or that they are present but at such low concentrations that the appropriate regulatory levels could not possibly be exceeded, the TCLP need not be run.

1.3 If an analysis of any one of the liquid fractions of the TCLP extract indicates that a regulated compound is present at such high concentrations that, even after accounting for dilution from the other fractions of the extract, the concentration would be above the regulatory level for that compound, then the waste is hazardous and it is not necessary to analyze the remaining fractions of the extract.

1.4 If an analysis of extract obtained using a bottle extractor shows that the concentration of any regulated volatile analyte exceeds the regulatory level for that compound, then the waste is hazardous and extraction using the ZHE is not necessary. However, extract from a bottle extractor cannot be used to demonstrate that the concentration of volatile compounds is below the regulatory level.

2.0 SUMMARY OF METHOD

2.1 For liquid wastes (i.e., those containing less than 0.5% dry solid material), the waste, after filtration through a 0.6 to 0.8 μm glass fiber filter, is defined as the TCLP extract.

2.2 For wastes containing greater than or equal to 0.5% solids, the liquid, if any, is separated from the solid phase and stored for later analysis; the particle size of the solid phase is reduced, if necessary. The solid phase is extracted with an amount of extraction fluid equal to 20 times the weight of the solid phase. The extraction fluid employed is a function of the alkalinity of the solid phase of the waste. A special extractor vessel is used when testing for volatile analytes (see Table 1 for a list of volatile compounds). Following extraction, the liquid extract is separated from the solid phase by filtration through a 0.6 to 0.8 μm glass fiber filter.

2.3 If compatible (i.e., multiple phases will not form on combination), the initial liquid phase of the waste is added to the liquid extract, and these are analyzed together. If incompatible, the liquids are analyzed separately and the results are mathematically combined to yield a volume-weighted average concentration.