



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

JUL 16 2001

Mr. Gary Chilcott
CEO/President
Sure-Way Systems, Inc.
310 East Harry Bridges Boulevard
Wilmington, CA 90744

Ref. No. 01-0067

Dear Mr. Chilcott:

This is in response to your letter and telephone conversations with members of this office asking if your company's new reusable sharps container satisfies the packaging requirements for the transport of "Regulated medical waste, 6.2, UN 3291, PG II" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You stated that this new container is a modification of the container described in your April 16, 2000 letter and our October 18, 2001 response.

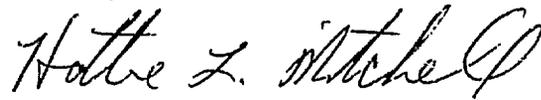
The following is your description of the modified packaging. The packaging has sharps container of rigid, oblong, high-density polypropylene, 2 to 4 gallons in size, with a locking lid. Flanges extending from the edge of the container lid are designed to be attached to, and suspended from, a 4-wheeled metal cart rack that is 28 inches wide and 4 feet long at its base. Metal bars placed at the ends of the cart rack where the containers are loaded and unloaded are locked during transportation. The cart is made of a lighter steel frame, has 1/8-inch fiberglass panels attached to the sides and top and a vacuum molded 1/8-inch thick plastic pan with a 12-gallon capacity placed at the bottom. The modified packaging does not have absorbent material in the bottom of each sharps container and does not have 1/8-inch thick polyethylene sheeting surrounding the top, bottom, and sides of the cart.

You state the cart's markings conform to the requirements of the Department of Transportation's HMR for the UN 3291, PG II, material and the Federal Drug Administration (FDA). You also state the sharps container is not to be used for cultures and stocks, and passes FDA's drop, puncture and tip tests. You enclosed photographs that appear to show the cart racks marked with the Occupational Safety and Health Administration (OSHA) "BIOHAZARD" marking. You did not describe the packaging as still meeting OSHA's requirements in 29 CFR 1910.1030, as required by 49 CFR 173.134(b)(3)(ii)(B). Therefore, it is our opinion that the modified polypropylene container would be acceptable only if it meets the requirements in § 173.134(b)(3), including the

general requirements in §§ 173.24 and 173.24a. Section 173.24(f) specifically requires that the closures on the packaging be designed and closed so that there is no identifiable release of hazardous material to the environment from the opening to which the closure is applied and that the closure be secure and leakproof.

I hope this satisfies your request.

Sincerely,

A handwritten signature in cursive script that reads "Hattie L. Mitchell". The signature is written in black ink and is positioned to the right of the typed name.

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Edmonson
§ 173.134
Packagings

01-0067



SURE-WAY SYSTEMS, INC.

Hattie L Mitchell
Chief Regulatory Review and Reinvention
Office of Hazardous Materials Standards
Ref No. 00-0128

February 14, 2001

Dear Ms. Mitchell

Thank you for your letter of October 18, 2000 concerning our sharps container DOT approval. Since writing that letter, we have refined our transportation process of containers. We ask that you revise your letter of October 18th to reflect the final transportation process. Our containers are the same as in our original request with the exception of the absorbent pad. This has been eliminated since it is not required by OSHA. We are enclosing the testing documentation showing that the containers have been tested and meet the OSHA requirements in 29 CFR 1910.1030 (as well as certain other performance criteria).

The transport cart has been modified by taking away the enclosed sides and side door making it an end loading/unloading cart for improved security, ease of movement through the hospital, and processing at the plant. The stainless steel racks hold 64 -2 gallon containers or 48 -4 gallon containers. The containers are secured in the cart so as not to tip over or fall out of the rack. The rack is on four wheels and is 28" wide and 4" long. The two changes, one to the container and one to the cart, do not seem to be pertinent to your decision that our containers meets the standards laid out in your attached letter of October 18th.

I am enclosing your letter of October 18th and the test results so your review may be expedited a little. Thank you for your clarification of this modification in your first response letter. We are happy with the system, as are our hospitals.

Respectfully Submitted,

Gary Chilcott Pres/CEO

Sure-Way Systems, Inc.

P.O. Box 899 Deer Lodge, Montana 59722 office 208 Missouri Ave. 1-800-822-3929 / (406) 846-7842 FAX

202 300 3012





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ENGINEERING REPORT NO. 24961-1

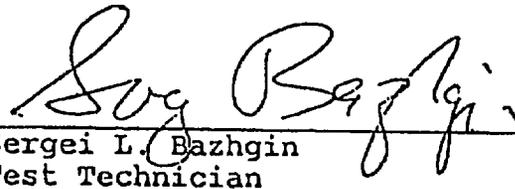
"CONTAINER TEST"

19 July 1999

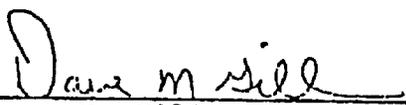
for

SURE-WAY SYSTEMS, INC.
310 Harry Bridges Boulevard
Wilmington, California 90744

Prepared by:


Sergei L. Bazhgin
Test Technician

Approved by:


Dave M. Gillen
Vice President & Manager

PREPARED FOR: SURE-WAY SYSTEMS, INC. 310 Harry Bridges Boulevard Wilmington, CA 90744	19 July 1999
	Environ No. 24961-1
	P.O. No. 13141

CONTAINER TEST

1. ABSTRACT

1.1 Object

Subject four (4) Reusable Sharp Containers to the tests described in Enclosure E-1 of the 510K Notification, which references DOT 49CFR, Section 178.603, ASTM Task Force F04.65.01, Draft #12, dated 6/11/92, and ANSI Z535.

1.2 Conclusions

The four Reusable Sharp Containers met the requirements of the Enclosure "Sure-Way Systems, Inc. Sharp Container 510(K) Test Protocol" and successfully passed all the tests described in this Enclosure.

2. UNITS TESTED

MANUFACTURER:	N/A
DEVICE:	Four (4) Reusable Sharp Containers
MODEL NO.:	N/A
SERIAL NO.:	N/A

3. TEST REQUESTED

Subject four (4) Reusable Sharp Containers to the Overfull Detection, Leak Resistance, Mounting Accessories, Sharp Access and Closure, Capacity, Impact Resistance, Puncture Resistance, Identifications-Labeling, and Feature to Minimize Aerosolization Testing, in accordance with Sure-Way Systems, Inc. Sharp Container 510(K) Test Protocol.

4. INSTRUMENTATION, PROCEDURE AND RESULTS

4.1 Instrumentation

All instrumentation is calibrated regularly by methods directly traceable to the National Institute of Standards and Technology, and in accordance with MIL-STD-45662A, MIL-I-45208A, and ANSI/NCSL Z540-1-1994.

INSTRUMENT	MFG/MODEL	ENVIRON NO.	RANGE	ACCURACY
Ultrasonic Thickness Gauge	Parametrics 26 MG S/N 9803446	Calibration: Last: 19 Jun 98 Due: 19 Jun 00	0.02" - 20"	± 2% reading
Transducer	Parametrics D799 S/N 109623	Calibration: Last: 7 Jul 99 Due: 1 Jan 00	0.04" - 0.3"	± 2%
Steel Rule	L.S. Starrett 404R	740-029 Calibration: Last: 30 Nov 98 Due: 30 Nov 99	0-48"	± 1/64"
Universal Testing Machine	Instron 1125	740-054	0 to 20,000 lbs.	N/A
Tensile Cell	Instron A217-12	745-013 Calibrate before use	0 to 1,000 lbs.	± 0.5% reading
Weight Set	Ashcroft 1305B	710-184 Calibration: Last: 6 Jan 98 Due: 6 Jan 00	10-100 OZ 26 PC	± 0.5% SP
Graduated Cylinder	Fisher, Nagle 3663-0500	490-035 Calibration: Last: 1 Jan 97 Due: 1 Jan 02	0-500 ml	± 2.6 ml

4. INSTRUMENTATION, PROCEDURE AND RESULTS (Cont'd.)

4.2 Procedure (Cont'd.)

4.2.5 STABILITY

The container mounting bracket was fastened to a plywood board. The board was rotated and/or tilted until the Sharp container toppled. The four reusable Sharp containers did not topple because of the bracket construction. Then the four reusable Sharp containers were positioned on a flat floor without the bracket. All four containers remained stable without tipping in accordance with OSHA Specification 29 CFR 1910.1070.

4. INSTRUMENTATION, PROCEDURE AND RESULTS (Cont'd.)

4.1 Instrumentation (Cont'd.)

INSTRUMENT	MFG/MODEL	ENVIRON NO.	RANGE	ACCURACY
Temperature Recorder	Partlow MRC 7000	200-094 Calibration: Last: 7 Jul 99 Due: 1 Jan 00	-150 to +200°F	± (0.25% reading + 1°F)
Single Pan Balance Scale	Ohaus Galaxy 4000 DO	730-015 Calibration: Last: 29 Dec 98 Due: 29 Dec 99	0-4000 grams	± 0.03 grams

4.2 Procedure

The test units were conditioned for a minimum of 24 hours at 72°F prior to testing.

4.2.1 IMPACT RESISTANCE

The four reusable Sharp containers were filled with simulated medical waste provided by customer. Each container was filled $\frac{3}{4}$ full with assorted sharp items and needles attached to hypodermic syringes. The weight of medical waste was 3.76 lb. Then each container was dropped from a height of 39" to the base onto a concrete floor. No fractures or loss of contents were detected during testing of the four containers.

4.2.2 CAPACITY

4. INSTRUMENTATION, PROCEDURE AND RESULTS (Cont'd.)

4.3 Results

The four Reusable Sharp Containers met the requirements of the Enclosure "Sure-Way Systems, Inc. Sharp Container 510(K) Test Protocol", based on proposed ASTM Standard F04 65.01, the BSI Standard (BS7320:1990) and OSHA Specification (29 CFR Section 1910.1030) and successfully passed all the tests described in this Enclosure.

Appendix

To

Environ Engineering report No 24961-1

Container test

Penetration force, volume

Table of Results for Engineering report No 24961-1

Container test

sample No	Location	Thickness, Inches	Penetration Force 1, Lbs	Penetration Force 2 Lbs	Penetration Force 3 Lbs
	1 lid	0.11	7.0	8.75.	14.50.
	2 lid	0.101	8.0	8.84.	8.80.
	3 lid cover	0.114	10.03.	11.05.	10.20.
	4 lid cover	0.112	10.04.	10.40.	10.80.
	5 body	0.120	10.07.	11.70.	10.00.
	6 body	0.122	12.07.	10.20.	11.20.
	7 body	0.121	13.80	12.50.	10.50.

Penetration Test

Cont. No	Volume, liters
1	14.5.
2	14.5.
3	14.5.
4	14.5.

Volume test