TECHNOTES
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A study monitoring

In-Use 70% Isopropyl Alcohol Level

Using a specific Gravity Method Test ►

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A study monitoring the in-use **70% Isopropyl Alcohol Level** using a specific Gravity Method Test

Introduction

IPA solution is a mixture of 70% by volume USP-grade Isopropanol (isopropyl alcohol, IPA) and 30% USP-purified water. This solution is submicron filtered, filled into cleaned containers, and double-bagged. Texwipe offers several products containing 70% Isopropyl Alcohol solution. Some of these are gamma-irradiated (see the product offering in Appendix 1) to make sterile 70% IPA alcohol products. All bottles, sterile or non-sterile, are lot coded with an expiration date for easy recordkeeping. Spray bottles come complete with an adjustable trigger head with options for stream delivery or coarse spray. All bottles come ready for use, fully-assembled with no extra steps required.

Isopropyl Alcohol solutions are intended to be used for cleaning and residue removal:

- Cleaning general surfaces
- Pre-cleaning before disinfectant application
- Removing residues after disinfectant application
- Cleaning gloved hands
- Wiping down items for pass through to controlled environments

Bottles of IPA solution are sometimes used over several days. It is important to know if the concentration of the IPA in solution is varying as it is used.

Purpose

Since Texwipe's Sterile 70% by volume USP-grade IPA products are offered meeting the USP Isopropyl Rubber Alcohol Monograph, it is important to document the IPA concentration stability as a function of time. A study was implemented to monitor the IPA concentration over 28 days after the bottle was opened to simulate in-use conditions. A recommended in-use shelf-life is intended to provide assurance of the appropriate quality of 70% IPA the product throughout its use by demonstrating compliance with USP's Monograph for Isopropyl Rubbing Alcohol.

Experimental

Six 16-oz bottles of Texwipe's Sterile 70% Isopropanol TX3270 were set aside for the study and were kept under laboratory conditions, room temperature (20°C) and pressure (one atmosphere). The specific gravity was measured using a Mettler-Toledo International, Inc. (Columbus, OH) Densito 30PX on the first, seventh, fourteenth and twenty eighth days after opening the bottle. The meter displayed the specific gravity at 20°C/20°C conditions. As part of the study, each sample bottle was sprayed six or seven times each day over the course of the study. The specific gravity for each bottle was measured twice on the indicated test days.

Results

Specific gravity is a unitless number which is the ratio of the density of the substance and the density of water. Since density and the specific gravity are affected by temperature, the conditions at which the densities were measured are specified. The typical format is in the style of a fraction, e.g., 20°C/20°C. The left value references the temperature for the substance, and the right value references the temperature for the water.

Specific gravity is commonly used to determine the concentration of substances in solutions. The concentration of the isopropyl alcohol in the isopropyl alcohol – water solution was determined by locating the measured specific gravity in a table and referencing the percent volume (% Volume) in the isopropyl alcohol solution with that specific gravity. The specific gravity and its corresponding percent volume isopropyl alcohol used for this study are compiled in Table 1.

Table 1

Specific gravity of Isopropyl Alcohol

% Volume	Specific Gravity
67.7	0.884
68.0	0.883
68.4	0.882
68.8	0.881
69.2	0.880
69.6	0.879
69.9	0.878
70.3	0.877
70.7	0.876
71.1	0.875
71.4	0.874
71.8	0.873
72.2	0.872

Table 1. Specific gravity (20°C/20°C) of Isopropyl Alcohol – Water Mixtures1 in the Range for Isopropyl Alcohol Concentrations Acceptable to the USP Rubbing Alcohol Monograph

The periodic specific gravity (20°C/20°C) test results for the study are compiled into Table 2. The specific gravity for each bottle was measured twice on each test day. In Table 2, the first measurement result of the specific gravity is indicated with an "R1" in the Sample Number and Measurement column. The second result is indicated with an "R2." The % volume result is determined through the use of the specific gravity – percent volume data found in Table 1.

Table 2

Sample Number & Measurement	Day 1		Day 7		Day 14		Day 28	
	Specific gravity	% Volume	Specific gravity	% Volume	Specific gravity	% Volume	Specific gravity	% Volume
Bottle 1 R1	0.877	70.3	0.877	70.3	0.877	70.3	0.877	70.3
Bottle 1 R2	0.877	70.3	0.877	70.3	0.877	70.3	0.877	70.3
Bottle 2 R1	0.877	70.3	0.877	70.3	0.877	70.3	0.877	70.3
Bottle 2 R2	0.877	70.3	0.877	70.3	0.877	70.3	0.877	70.3
Bottle 3 R1	0.878	69.9	0.878	69.9	0.878	69.9	0.878	69.9
Bottle 3 R2	0.878	69.9	0.878	69.9	0.878	69.9	0.878	69.9
Bottle 4 R1	0.878	69.9	0.878	69.9	0.878	69.9	0.878	69.9
Bottle 4 R2	0.878	69.9	0.878	69.9	0.878	69.9	0.878	69.9
Bottle 5 R1	0.878	69.9	0.878	69.9	0.878	69.9	0.878	69.9
Bottle 5 R2	0.878	69.9	0.878	69.9	0.878	69.9	0.878	69.9
Bottle 6 R1	0.877	70.3	0.877	70.3	0.877	70.3	0.877	70.3
Bottle 6 R2	0.877	70.3	0.877	70.3	0.877	70.3	0.877	70.3

Table 2. Specific Gravity (20°C/20°C) Experimental Results for Six 70% IPA Bottles Measured on Four Test Days Ranging from One to Twenty-eight Days with Its Corresponding Percent Volume Isopropyl Alcohol

Discussion

The two specific gravity values measured for a specific bottle and day are repeatable. The values were identical. For each bottle, the specific gravity did not change from the first day (Day 1) to the last day (Day 28) of the study. The overall specific gravity values complied with the range (68% to 72%) found in the USP Isopropyl Rubbing Alcohol Monograph.

Conclusion

The study showed that the specific gravity and the corresponding % volume IPA did not change for six bottles measured over 28 days under in-use conditions (repetitive sprays each day of the study duration). The specific gravity and % volume values complied with the values found in USP's Monograph for Isopropyl Rubbing Alcohol.

Texwipe's 70% Isopropyl Alcohol solutions may be used for at least 28 days without concern for percent IPA concentration changing.

For additional information, please contact Texwipe Customer Service at the number listed below.

Customer Service

+1.336.996.7046

Visit us at www.texwipe.com

Reference

1. Specific gravity for varied Isopropyl alcohol – water solutions http://www.pharmcoaaper.com/pages/TechLibrary/tech_docs_high_purity_solvents_reagent_chem/specific_gravity_isopropyl_alcohol_water_mix.pdf , accessed January 12, 2015.

Appendix 1.

Texwipe's Isopropyl Alcohol Sterile and Non-Sterile Product Offering.

Part Number	Description	Packaging
Sterile 70% IPA		
TX3270	Sterile 70% Isopropanol trigger spray 16 fluid ounces (473 mL)	12 bottles/case
TX3273	Sterile 70% Isopropanol trigger spray 32 fluid ounces (946 mL)	12 bottles/case
TX3274	Sterile 70% Isopropanol trigger spray 16 fluid ounces (473 mL)	4 bottles/case
TX8270	Sterile 70% Isopropanol trigger spray 8 fluid ounces (237 mL)	12 bottles/case
TX3290	Sterile 70% Isopropanol 1 gallon (3.8 liters) polybottle	4 bottles/case
Non-Sterile 70% IPA		
TX167	Non-Sterile 70% Isopropyl Alcohol 16 fluid ounces (473 mL) trigger spray	12 bottles/case
TX117	Non-Sterile 70% Isopropyl Alcohol 1 gallon (3.8 liters) polybottle	4 bottles/case
Non-Sterile 100% IPA		
TX161	Non-Sterile 100% Isopropyl Alcohol 16 fluid ounces (473 mL) trigger spray	12 bottles/case
TX111	Non-Sterile 100% Isopropyl Alcohol 1 gallon (3.8 liters) polybottle	4 bottles/case