

Liquid Chromatography

Author

Nonie Danna

PerkinElmer, Inc.
Waltham, MA USA

Analysis of 'Broad Spectrum' UVA and UVB Components in Sun Care Products for Compliance with New FDA Regulations

Introduction

The FDA has made changes to how products containing sunscreen are labeled in the U.S. to ensure they meet the new regulations set forth for safety and effectiveness. The new regulations will require companies that want to use the 'Broad Spectrum' label to test for both UVA and UVB protection. The FDA's standardized test for broad spectrum enables consumers to determine the

level of UVA protection a sunscreen provides in addition to its ultraviolet B (UVB) radiation protection. Previous rules only dealt with preventing sunburn which is primarily due to UVB radiation but did not address UVA which protects against early aging and skin cancer. These new testing and labeling requirements are necessary to educate consumers and provide information for consumers to make knowledgeable choices. All products that claim to provide Broad Spectrum SPF protection are regulated as sunscreen products. Therefore, the regulations the FDA has developed for Over The Counter (OTC) sunscreen products apply to cosmetics, moisturizers, lip balms, and shampoos labeled with SPF values.

Experimental Conditions

Instrument: PerkinElmer FX-10 UHPLC System with Photo-Diode Array Detector
Series 200/Flexar PerkinElmer HPLC with UV/Vis Detector and Optimization Kit

Standard Preparation:

Prepare standard by weighing 50 mg standard into 10 mL isopropyl alcohol (IPA). A further 1:10 dilution is made using acetonitrile (ACN) as a diluent. Heat as needed to get into solution.

Sample Preparation:

Prepare sample by weighing 0.7 g into 10 mL IPA. Heat at 50 °C as needed to dissolve. Then take 0.8 mL prepared sample and dilute in 10 mL ACN. Filter with 0.45 µm syringe filter and inject. Most sample matrices are miscible in isopropyl alcohol.

Analysis Conditions:

Mobile Phase: A. (10%) 1.25% Acetic Acid in Water
B. (90%) Acetonitrile

Flow Rate: 0.60 mL/min

Injection Volume: 4 µL

Temperature: 25 °C

Detector: UV at 320 nm

Run time: 3.5 minutes

Column: PerkinElmer Brownlee SPP C18,
100 mm x 3.0 mm x 2.7 µm

Ordering Information

Description

Column Brownlee SPP
2.7 µm C18 3.0 mm x 100 mm

Series 200/Flexar UV/Vis Optimization Kit

Syringe Filter 0.45 µm x 25 mm

Part No.

N9308410

N2920191

02542905

References

U.S. Food and Drug Administration, 2012. Information for Consumers, 2012. Retrieved from <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm258468.htm>

PerkinElmer, Inc.
940 Winter Street
Waltham, MA 02451 USA
P: (800) 762-4000 or
(+1) 203-925-4602
www.perkinelmer.com

Results

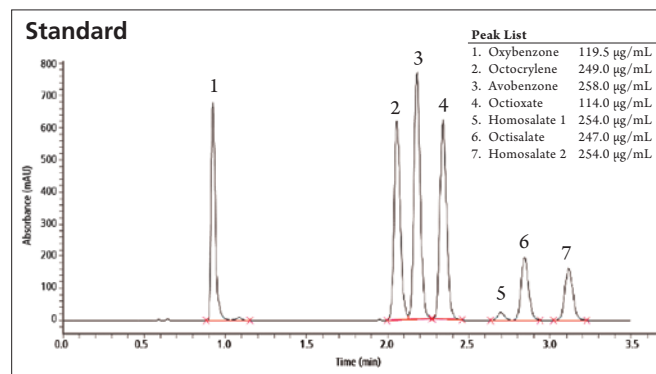


Figure 1. All UVA and UVB compounds are eluted in a single run using a Brownlee SPP column with an optimized PerkinElmer HPLC system.

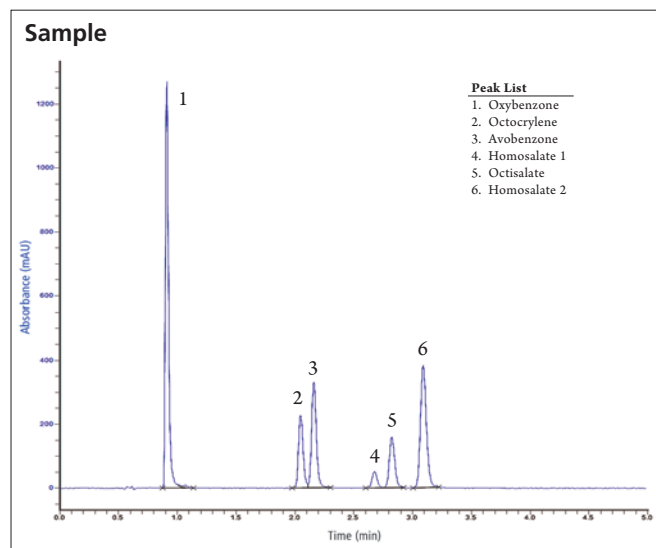


Figure 2. SPF 50 sun care spray shows elution of both UVA/B compounds.

Conclusion

The methodology in Figure 1 provides one test method to determine both UVA and UVB compounds most commonly used in the sun care industry. All UVB and UVA compounds are eluted in a single run and can be quantitated in the ranges recommended by the FDA (SPF 15-50+). Sun care products that pass the FDA's broad spectrum test procedure, which measures a product's ultraviolet A (UVA) protection relative to its ultraviolet B (UVB) protection, may be labeled as "Broad Spectrum SPF". Only Broad Spectrum products with an SPF value of 15 or higher can claim to reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures.



For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

Copyright ©2012, PerkinElmer, Inc. All rights reserved. PerkinElmer® is a registered trademark of PerkinElmer, Inc. All other trademarks are the property of their respective owners.