



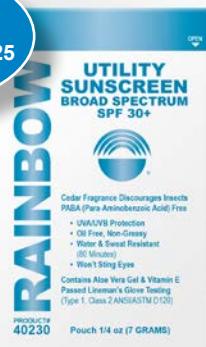
# Utility Sunscreen

## Broad Spectrum (UVA/UVB) SPF 30+

**PRODUCT #**  
**4022**  
**40223**  
**40230**

### Products currently offered

**NEW!**  
**#40230 Lotion**  
Pack replaces #40225  
Towelettes



Same great formula,  
now in a lotion application

**Single-Application Pack**  
**#40230**



**4-oz. Bottle**  
**#4022**



**2-oz. Pump Bottle**  
**#40223**

The Food and Drug Administration has determined that towelettes or wipes are not an acceptable format for sunscreen products. Therefore, we will be replacing #40225 towelette with #40230 single-application packs containing 0.25-oz. of sunscreen lotion. This will be in addition to our #4022 4-oz. bottle and the #40223 2-oz. pump bottle.

Below is an excerpt from the notice detailing the ruling:

SUMMARY

The 2011 ANPR (Advance Notice of Proposed Rulemaking) also listed those dosage forms that we did not consider currently eligible for review for potential inclusion in the OTC sunscreen monograph:

- wipes
- towelettes

Over-the-Counter (OTC) sunscreen products in these dosage forms are not currently eligible for review under the OTC sunscreen monograph, because we lack the evidence that such products existed in the OTC drug marketplace on or before May, 1972. OTC sunscreen products in these dosage forms also have not established eligibility for review under the Time and Extent Application (TEA) process (21 CFR 330.14(c)), because we have not received any TEAs for these products. (That regulation specifies the process and content for establishing eligibility for OTC drugs initially marketed in the United States after the OTC Drug Review began in 1972, or with no U.S. marketing experience.) OTC sunscreen products in these dosage forms that are marketed without an approved application therefore remain liable to regulatory action unless and until the requirements of § 330.14(h) are satisfied.

The new sunscreen pack will offer the same Broad Spectrum UVA/UVB SPF 30+ protection in a convenient, single-application pack. For more information on this product, contact your Rainbow Technology representative or visit our website at [www.RainbowTech.net](http://www.RainbowTech.net).