



# AccountAbility

Setting the Standard for Sustainability



Independent Assurance on Internal Processes, Procedures, Systems, Controls and Standard Operating Procedures at Bayer Around Quality, Safety and Efficacy Aspects of the Coppertone® Products

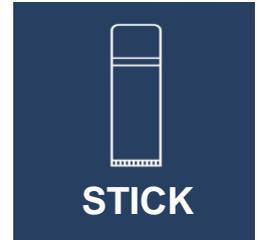
## Assurance Scope

BAYER engaged AccountAbility to undertake an independent assurance to assess the labeling accuracy of the **Coppertone® products** (the “Products”). The assessment determines that all applicable **standard operating procedures** (“SOPs”), which reflect regulatory and industry guidelines, are adhered to as part of Bayer’s processes, systems and controls to ensure the **quality, safety, and efficacy** aspects of the Products, including **sourcing, supplier audits, pharmacovigilance**, etc. See page 3 for more details.

We have performed **limited assurance** procedures in accordance with **ISAE3000 (Revised)** – the International Standard on Assurance Engagement, as well as **Type 2 Moderate** assurance procedures in accordance with the AccountAbility Assurance Standard (2008) – **AA1000AS**.

The scope of our work is limited to the Products released in the United States for the period **January 1, 2017 through December 31, 2017**.

## Product Forms



## Product Profile Selected for Assurance Procedures



The sun protection factor “SPF” for all Coppertone products ranges from 6-100. AccountAbility **selected a sample of 10 Products** sold in 2017 to conduct its assurance procedures. These 10 products exhibit the following **SPF profile and product categories**, which represent **over 85%** of all units sold in the calendar period.

### Product Categories



★ Represents SPF of the selected products

## Research

The AccountAbility Institute focuses on providing clients with critical insights to anticipate evolving challenges.

## Standards

The AA1000 series are principles-based standards and frameworks that help organizations demonstrate leadership in sustainability.

## Advisory

AccountAbility helps its clients improve their sustainability performance by providing practical and impactful solutions.

## ASSURANCE STANDARDS

### AA1000 AS

#### INCLUSIVITY

How Bayer identifies and includes participation of stakeholders in developing and achieving an accountable and strategic response to the subject matter.

#### MATERIALITY

How Bayer determines the relevance and significance of an issue to an organization and its stakeholders.

#### RESPONSIVENESS

How Bayer responds to stakeholder issues that affect its performance, realized through actions, decisions and communications.

### ISAE3000

#### QUALITY

How Bayer's SOPs are applied to ensure the defined quality requirements by internal and external stakeholders are met.

#### SAFETY

How Bayer's SOPs are applied to ensure the defined safety requirements by internal and external stakeholders are met.

#### EFFICACY

How Bayer's SOPs are applied to ensure the defined efficacy requirements by internal and external stakeholders are met.

SPF

## Assurance Process

### ASSESS

### DESIGN

### EXECUTE

### COMMUNICATE

BAYER STANDARD OPERATING PROCEDURES

FDA 2011 MONOGRAPH

ICH STANDARDS

ISO:24443:2012

APPROVED PROTOCOLS

EVIDENTIAL SUPPORT

AA1000AS & ISAE3000

Assurance Procedure



TESTING

INSPECTION

OBSERVATION

CONFIRMATION

INQUIRY



- ✓ Quality
- ✓ Safety
- ✓ Efficacy
- ✓ Inclusivity
- ✓ Materiality
- ✓ Responsiveness

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## Assurance of Bayer's Processes



## Independent Assurance Result

Based on inquiries and evidence obtained, **nothing has come to our attention** that causes us to believe that Bayer has not, for the scope period spanning **January 1 2017 through December 31, 2017**:

- Adopted, in all material respects, its Standard Operating Procedures and guidelines that adhere to the AccountAbility Principles 2008 – AA1000APS.
- Complied with Bayer's interpretation of international industry standard guidelines as well as internal procedures designed to deliver quality, safety and efficacy of its Products.
- Appropriately implemented quality assurance procedures, based on its interpretation of market regulation for the United States as related to the active ingredients, sun protection factor ("SPF"), water resistance, stability and broad spectrum properties on the label and packaging of the selected 10 Products.
- Verified the work undertaken by third parties to comply with market regulations in the United States related to the quality, safety and efficacy of the Products.
- Accurately labeled the ingredients, expiry dates and made appropriate claims on the packaging of its Products.

**\* DISCLAIMER:** This report is intended to summarize the assurance engagement undertaken for informational purposes. For the complete assurance report and conclusion, please refer to Bayer Consumer Health Division website.