



February 2015

PRODUCT ANNOUNCEMENT
Globally Harmonized System Update

Dear Beckman Coulter Customer,

As previously communicated in January 2014, Beckman Coulter is in the process of updating our product labeling, Safety Data Sheets (SDS), and Instructions for Use (IFU) to align with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Descriptions of these requirements are summarized below.

Product Labeling and Documentation Changes

Hazard classification:

Manufacturers and importers are required to determine the hazardous nature of the chemicals and products they produce or import. Hazard classification under the GHS standard provides specific criteria to address health, physical, environmental hazards.

Labels:

Manufacturers and importers must provide label elements consistent with the GHS requirements including a signal word, pictogram, hazard statement and precautionary statement for each hazard class and category.

Instructions for Use:

IFUs will be updated to align with any changes to labeling. Beckman Coulter will maintain previous hazard classifications in IFUs, along with new GHS hazard classifications, so you will have access to both as we transition the classification of products in the field.

Safety Data Sheets:

Formally known as Material Safety Data Sheets (MSDS), the new SDS format requires 16 specific sections, ensuring consistency in presentation of important chemical information. The GHS label elements will be added to section 2.

Webpage and Communications

As part of our continuing commitment to our customers, Beckman Coulter has launched a webpage dedicated to GHS. On the webpage, you will be able to find information regarding:

- The background of GHS
- The impact of GHS on Beckman Coulter products

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- Downloadable examples and guides related to Safety Data Sheets, Instructions for Use, Labels, and GHS pictograms
- Web links to various regulatory agency sites where further information on GHS can be found

We hope you will find this page both informative and useful. The GHS Webpage can be found by going to the following URL: [www.beckmancoulter.com\GHS](http://www.beckmancoulter.com/GHS)

As GHS changes are implemented, you may receive future communications specific to the Beckman Coulter products you purchase. These letters will describe the changes to those products in further detail.

By June 1st, 2015, updated Instructions for Use and Safety Data Sheets containing the required GHS elements and classifications will be available via the <http://techdocs.beckmancoulter.com> website for the Beckman Coulter line of products. If you have not already done so, we encourage you to register on the My Technical Documents section of the website. Once registered, you will be able to subscribe to receive regular email updates of the latest revisions for any documents your lab may require.

If you have any questions regarding these updates, please contact your local Beckman Customer Support Center.

Thank you for your continued support of Beckman Coulter products and services.

Sincerely,



Steven C de Baca
Senior Vice President, Quality & Regulatory Affairs
Beckman Coulter Diagnostics

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