No. VL01-0000000910
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お客様各位

株式会社ベリタス
バイオサイエンス本部
技術グループ　マネージャー　横沢 佑弥
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Celsis 試薬 化学組成変更および商品コード変更のお知らせ

拝啓

平素より Charles River 社商品をご利用いただきありがとうございます。

微生物迅速試験システム「Celsis」のマンスリーメンテナンス試薬につきまして、製造時における原材料の入手場所変更に併ない、試薬の化学組成が変更されますのでお知らせいたします。つきましては弊社商品コードも変更させていただきます。

なお、試薬の化学組成変更による試薬性能へは影響はございません。

今後とも弊社および Charles River 社商品をよろしくお願い申し上げます。

【対象商品名および商品コード】

Maintenance & Cleaning kit for advance (CLS92828)

【変更内容】

Reagent1(C93784)の原材料の入手場所変更に伴い、原材料を同等の物質に代替しました。このため Reagent1 より四ホウ酸二ナトリウム十水和物（CAS#1303-96-4）が除外されます。またサチライシン（CAS#9014-01-1）の含有量が 0.06%に変更になります。

変更後の試薬には労働安全衛生法（安衛法）の SDS 表示対象であるプロパン－1,2－ジオール（CAS # 75-55-6）を含むことから、該当の SDS を掲載いたします。

なお、その他の試薬（Reagent2 および 3）の変更はございません。

Charles River 社では新しい原材料で製造された試薬の品質試験を実施し、変更後の試薬の品質特性が従来の試薬と同等であることを確認しています。

また化学組成変更にともない、商品コードを下記に変更いたします。商品名や規格に変更はございません。

現商品コード	新商品コード
CLS92828	CLSC92828

【変更時期】

2025 年 8 月製造分の Reagent1 を含むキットより変更 ※弊社への入荷時期は 1 月下旬以降となります。

現商品コードの試薬は弊社在庫がなくなり次第、販売終了となります。

メーカー文書および SDS もご参照ください。

ご不明な点がございましたら、技術グループ（03-5776-0040 または tech_support@veritastk.co.jp）までお問合せ下さい。

以上

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www.criver.com

Title of Change: Celsis® - Reagent 1 (C93784) Formulation Change

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Charles River strives to provide the highest level of support to our customers by delivering industry-leading scientific and technological advances. As part of our ongoing effort to better serve our customers, we want to inform you of an upcoming change to Reagent 1 (C93784) included in the Monthly Maintenance and Cleaning Kit (C92828).

Description of Change:

The Maintenance and Cleaning Kit is intended to eliminate microbial contamination from the Celsis Advance II™ and Celsis Accel® instruments. The Maintenance and Cleaning Kit contains 3 reagents:

Reagent 1, which dissolves any precipitate present in the injector tubing
Reagent 2, which eliminates microbial contamination
Reagent 3, which flushes the injector tubing and removes any residue

Charles River Microbial Solutions Germany GmbH, which manufactures Celsis® reagents, is no longer able to source a raw material that is used in Reagent 1 (C93784) from a vendor in the United States. Due to this change in raw material availability, the decision was made to reformulate and substitute the material with an equivalent material. The substitute material will impact the classification according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The chemical, disodium tetraborate decahydrate will be removed in the updated formulation. In addition, the enzyme subtilisin is 0.06% weight of the overall formulation. According to CLP Regulation No. 1272/2008/EC, the mixture does not meet the criteria for classification, so the GHS pictograms and classifications will be removed from the SDS and bottle labels starting in August 2025.

Charles River has performed studies with manufactured development batches of Reagent 1 with the new formulation, and batches were tested in accordance with the existing Quality Test methods used for lot release of Reagent 1. This data generated confirms that the performance and critical quality attributes of the new formulation are equivalent to those of the legacy formulation.

Implementation Date:

Beginning in August 2025, Charles River Microbial Solutions Germany GmbH will begin manufacturing Reagent 1 using the new formulation. Please be advised that this transition will occur over time based on component stock levels and production schedules.

These changes **do not impact** your ordering process with Charles River, and there are no other changes to the impacted products other than those described above. The Celsis® reagents continue to be filled, freeze-dried, labeled, and packaged using the same equipment and documented on approved batch records. The methods and procedures used for quality control testing of each product and the process used by Quality Assurance to perform final release also remain unchanged.

The above changes have been made to ensure business continuity and Charles River's ongoing efforts for continuous improvement for Microbial Solutions products. There are many factors that contribute to our overall decision-making process regarding product changes, which include, but are not limited to, operational efficiencies, waste reduction and environmental considerations. If you have any questions, please contact Charles River Technical Support at Celsis-Support@crl.com.

Sincerely,

Signed by:
Brice Chasey
Signer Name: Brice Chasey
Signing Reason: I approve this document
Signing Time: 05-Sep-2025 | 08:09:42 EDT
278553CC06884703920C5585C41C79E1

Dept. Approval

Signature/Date_____

Brice Chasey

Associate Director, Product Management – Celsis®

Charles River Microbial Solutions

Signed by:
Maeve Purcell
Signer Name: Maeve Purcell
Signing Reason: I approve this document
Signing Time: 05-Sep-2025 | 07:03:40 EDT
0F0905ED1BEB490E9CE44E4BE85BC564

QA Approval

Signature/Date_____

Maeve Purcell

Senior Regulatory Compliance Manager

Charles River Microbial Solutions