




CHANGE NOTIFICATION

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| Notification number | PZ_2306_02 | Date | 14.06.2023 | | | | | |
| Change number | 098 | | | | | | | |
| Subject of the change | Classification and labelling change. | | | | | | | |
| Affected products | Cat no | Product name | | | | | | |
| | See: Attachment 1 | | | | | | | |
| Change category | <input type="checkbox"/> raw materials <input type="checkbox"/> quality control <input type="checkbox"/> packages <input checked="" type="checkbox"/> informations provided with the product <input type="checkbox"/> manufacturing <input type="checkbox"/> final product <input type="checkbox"/> other | | | | | | | |
| Change description | <p>The classification and labelling of:</p> <ul style="list-style-type: none"> • CHOL reagent (1-REAGENT), • aqueous standard CHOLESTEROL STANDARD 200 and 3-STANDARD (available as a part of Liquick Cor-CHOL 30 and Liquick Cor-CHOL 60 kits) <p>and labelling of:</p> <ul style="list-style-type: none"> • GLUCOSE reagent, • CRP-ULTRA reagent (1-REAGENT) <p>has been changed.</p> <p>The current labelling below:</p> <ul style="list-style-type: none"> • CHOL REAGENT <table border="1" data-bbox="574 1254 1388 1512"> <tr> <td style="text-align: center;"></td> <td> <p>Warning</p> <p>H319 Causes serious eye irritation. P280 Wear protective gloves, protective clothing, eye protection or face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> </td> </tr> </table> • AQUEOUS STANDARD (CHOLESTEROL STANDARD 200 / 3-STANDARD) <table border="1" data-bbox="574 1601 1388 1646"> <tr> <td>EUH210 Safety data sheet available on request.</td> </tr> </table> • GLUCOSE REAGENT <table border="1" data-bbox="574 1691 1388 1848"> <tr> <td> EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction. EUH210 Safety data sheet available on request. </td> </tr> </table> • CRP ULTRA REAGENT <table border="1" data-bbox="574 1892 1388 1937"> <tr> <td>EUH210 Safety data sheet available on request.</td> </tr> </table> | | |  | <p>Warning</p> <p>H319 Causes serious eye irritation. P280 Wear protective gloves, protective clothing, eye protection or face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> | EUH210 Safety data sheet available on request. | EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction. EUH210 Safety data sheet available on request. | EUH210 Safety data sheet available on request. |
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| EUH210 Safety data sheet available on request. | | | | | | | | |
| EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction. EUH210 Safety data sheet available on request. | | | | | | | | |
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| Reason for change | Fulfilling the requirements of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 taking into account Adaptation to Technical Progress (ATP) to the CLP Regulation. |
| Implementation | June 2023 |
| Additional information | Reagents and the aqueous standard with the new labelling will be available for sale beginning from mid-June 2023. Products with the old labelling may also be available – while stocks last. Once you receive the notification, follow the new classification of the reagents and the aqueous standard. Use personal protective equipment when working. Updated material safety data sheet (MSDS) is available at: https://cormaydiagnostics.com/ |
| Attachments | Attachment 1 - List of kit affected by the change |

If there are any questions or concerns with respect to this change, please feel to contact your Area Sales Managers

Quality Assurance Coordinator