

# F02-QAD-04\_01 / 20.07.2021

## **CHANGE NOTIFICATION**

Notification number	PZ_2309_02	Date	20.09.2023	
Change number	098			
Subject of the change	Classification and labelling change.			
Affected products	Cat no	Product name	Product name	
	6-251 6-254 6-252 6-256 6-259	CORMAY CRP L CORMAY RF La CORMAY RPR C	CORMAY ASO Latex 100 CORMAY CRP Latex 100 CORMAY RF Latex 100 CORMAY RPR Carbon 500 CORMAY TPHA 100	
Change category	<ul><li>□ raw materials</li><li>□ packages</li><li>□ manufacturing</li></ul>	<ul><li>☐ quality cont</li><li>☐ information</li><li>☐ final produc</li><li>☐ other</li></ul>	ns provided with the product	
Change description	The classification and labelling of agglutination tests has been changed:  CORMAY CRP Latex 100, CORMAY RF Latex 100, CORMAY RPR Carbon 500, CORMAY TPHA 100.  The current labelling below: CRP-Latex contains boric acid.  Danger H360FD May damage fertility. May damage the unborn child. P201 Obtain special instructions before use. P308+P313 IF exposed or concerned: Get medica advice. P405 Store locked up. CRP-Control (+) and CRP-Control (-) contain 2-methyl 2H-isothiazol-3-one.  Warning H317 May cause an allergic skin reaction. P280 Wear protective gloves, protective clothing, eye protection or face protection. P302+P352 IF ON SKIN: Wash with plenty of soar and water.			



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#### CORMAY ASO Latex 100:

ASO-Control (+) and ASO-Control (-) contain 2-methyl-2H-isothiazol-3-one.

#### Warning



H317 May cause an allergic skin reaction.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

#### CORMAY RF Latex 100:

RF-Control (+) and RF-Control (-) contain 2-methyl-2H-isothiazol-3-one.

#### Warning



H317 May cause an allergic skin reaction.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

#### CORMAY RPR Carbon 500:

RPR-Control (+) and RPR-Control (-) contain 2-methyl-2H-isothiazol-3-one.

#### Warning



H317 May cause an allergic skin reaction.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

#### CORMAY TPHA 100:

TPHA-Control (+) and TPHA-Control (-) contain 2-methyl-2H-isothiazol-3-one.

#### Warning



H317 May cause an allergic skin reaction.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

### 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.

# **QUALITY MANAGEMENT SYSTEM**





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Implementation	September 2023		
	Products with the new labelling will be available for sale beginning from September 2023. Products with the old labelling may also be available – while stocks last.		
Additional information	Once you receive the notification, follow the new classification of the reagents. Use personal protective equipment when working.		
	Updated material safety data sheets (MSDS) are available at: https://cormaydiagnostics.com/customer-support/documents		
Attachments	N/A		

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

**Quality Assurance Coordinator**