

F02-QAD-04_01 / 20.07.2021

CHANGE NOTIFICATION

Classification and labelling change.	Notification number	PZ_2306_03	Date	20.06.2023
Cat no	Change number	098		
2-180 CORMAY LDL DIRECT	Subject of the change	Classification and labelling change.		
2-191 CORMAY LDL DIRECT 30		Cat no	Product name	
2-192		2-180	CORMAY LDL DIRECT	
2-193		2-191	CORMAY LDL DIRECT 30	
7-280		2-192	CORMAY LDL DIRECT 60	
7-380		2-193	CORMAY LDL DIRECT 120	
7-480		7-280	ACCENT-200 LDL DIRECT	
4-180		7-380	ACCENT-300 LDL DIRECT	
4-490		7-480	A-400 LDL DIRECT	
4-569		4-180	PRESTIGE 24i LDL DIRECT	
9-412 OS-LDL DIRECT 5-509		4-490	PRESTIGE 24i LDL DIRECT	
S-509		4-569	HC-LDL DIRECT	
T-816		9-412	OS-LDL DIRECT	
Affected products B02-R0017		5-509	B50-LDL DIRECT	
Affected products 2-195_R1		7-816	A-800 LDL DIRECT	
Affected products 2-195_R2		B02-R0017	EQ LDL DIRECT	
2-179 CORMAY HDL DIRECT 2-181 CORMAY HDL DIRECT 30 2-182 CORMAY HDL DIRECT 120 4-183 CORMAY HDL DIRECT 120 7-279 ACCENT-200 HDL DIRECT 7-379 ACCENT-300 HDL DIRECT 7-479 A-400 HDL DIRECT 4-179 PRESTIGE 24i HDL DIRECT 4-179 PRESTIGE 24i HDL DIRECT 4-479 PRESTIGE 24i HDL DIRECT 4-579 HC-HDL DIRECT 9-411 OS-HDL DIRECT 5-508 B50-HDL DIRECT 5-508 B50-HDL DIRECT EQ HDL DIRECT B02-R0016 EQ HDL DIRECT 2-226_R1 CORMAY HDL DIRECT BULK CORMAY HDL DIRECT BULK CORMAY HDL DIRECT BULK □ raw materials □ quality control □ packages ■ informations provided with the product □ manufacturing □ final product		2-195_R1	CORMAY LDL DIRECT BULK	
2-181 CORMAY HDL DIRECT 30	Affected products	2-195_R2	CORMAY LDL DIRECT BULK	
2-182 CORMAY HDL DIRECT 60		2-179	CORMAY HDL DIRECT	
2-183 CORMAY HDL DIRECT 120 7-279 ACCENT-200 HDL DIRECT 7-379 ACCENT-300 HDL DIRECT 7-479 A-400 HDL DIRECT 7-815 A-800 HDL DIRECT 4-179 PRESTIGE 24i HDL DIRECT 4-479 PRESTIGE 24i HDL DIRECT 4-579 HC-HDL DIRECT 9-411 OS-HDL DIRECT 5-508 B50-HDL DIRECT 5-508 B50-HDL DIRECT 6		2-181	CORMAY HDL DIRECT 30	
7-279 ACCENT-200 HDL DIRECT A-379 ACCENT-300 HDL DIRECT A-400 HDL DIRECT A-400 HDL DIRECT A-800 HDL DIRECT A-800 HDL DIRECT A-800 HDL DIRECT PRESTIGE 24i HDL DIRECT A-479 PRESTIGE 24i HDL DIRECT A-579 HC-HDL DIRECT OS-HDL DIRECT B02-R0016 B02-R0016 CORMAY HDL DIRECT CORMAY HDL DIRECT BULK CORMAY H		2-182	CORMAY HDL DIRECT 60	
7-379 ACCENT-300 HDL DIRECT 7-479 A-400 HDL DIRECT A-800 HDL DIRECT PRESTIGE 24i HDL DIRECT PRESTIGE 24i HDL DIRECT A-579 HC-HDL DIRECT OS-HDL DIRECT B02-R0016 EQ HDL DIRECT CORMAY HDL DIRECT BULK D raw materials D quality control D packages D informations provided with the product D manufacturing D final product		2-183	CORMAY HDL DIRECT 120	
7-479 A-400 HDL DIRECT A-800 HDL DIRECT 4-179 PRESTIGE 24i HDL DIRECT PRESTIGE 24i HDL DIRECT A-579 HC-HDL DIRECT OS-HDL DIRECT S-508 B02-R0016 EQ HDL DIRECT CORMAY HDL DIRECT BULK CORMAY BULK CORMAY HDL DI		7-279	ACCENT-200 HDL DIRECT	
7-815		7-379	ACCENT-300 HDL DIRECT	
4-179 4-479 PRESTIGE 24i HDL DIRECT 4-579 HC-HDL DIRECT 9-411 OS-HDL DIRECT 5-508 B50-HDL DIRECT EQ HDL DIRECT CORMAY HDL DIRECT BULK 2-226_R1 CORMAY HDL DIRECT BULK □ raw materials □ quality control □ packages □ informations provided with the product □ manufacturing □ final product		7-479	A-400 HDL DIRECT	
4-479		7-815	A-800 HDL DIRECT	
A-579		4-179	4	
9-411 OS-HDL DIRECT 5-508 B50-HDL DIRECT EQ HDL DIRECT CORMAY HDL DIRECT BULK 2-226_R1 CORMAY HDL DIRECT BULK CORMAY HDL DIRECT BULK		4-479	PRESTIGE 24i HDL DIRECT	
S-508 B50-HDL DIRECT EQ HDL DIRECT EQ HDL DIRECT EQ HDL DIRECT EQ HDL DIRECT BULK CORMAY HDL DIRECT BULK CORMAY HDL DIRECT BULK raw materials quality control packages informations provided with the product manufacturing final product		4-579	HC-HDL DIRECT	
B02-R0016 2-226_R1 2-226_R2 Cormay HDL Direct Bulk		9-411	OS-HDL DIRECT	
2-226_R1 CORMAY HDL DIRECT BULK 2-226_R2 CORMAY HDL DIRECT BULK □ raw materials □ quality control □ packages □ informations provided with the product □ manufacturing □ final product		5-508		
2-226_R2 CORMAY HDL DIRECT BULK □ raw materials □ quality control □ packages ■ informations provided with the product □ manufacturing □ final product			4 · · · · · · · · · · · · · · · · · · ·	
Change category ☐ raw materials ☐ packages ☐ manufacturing ☐ final product ☐ product ☐ manufacturing ☐ control ☐ packages ☐ packages ☐ manufacturing ☐ final product				
Change category □ packages □ informations provided with the product □ manufacturing □ final product		2-226_R2	CORMAY HDL DIRECT BULK	
□ manufacturing □ final product	Change category	☐ raw materials		
☐ manufacturing ☐ final product		☐ packages	informations provided with the product	
		☐ manufacturing	☐ final product	
□ other			□ other	



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	The classification and labelling of reagents: LDL DIRECT and HDL DIRECT has been changed.			
	The current labelling below:			
Change description	1-REAGENTand 2-REAGENT contain reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). 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.			
Implementation	June 2023			
Additional information	Reagents 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. Use personal protective equipment when working. Updated material safety data sheet (MSDS) is available at:			
	https://cormaydiagnostics.com/			
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