

## Coloplast Products Containing Classified Phthalates




According to the European chemical legislation (REACH) Coloplast is obligated to inform about the products containing classified phthalates in concentrations above 0.1 % (w/w).

According to Coloplast phthalate policy we inform openly about products containing classified phthalates no matter how low the concentration is. These products will therefore appear in the list below.








According to the Medical Device Directive labelling is required if the medical devices

- are intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances.
- contain phthalates which are classified DEHP (diethylhexylphthalate), DBP (dibutylphthalate) and/or BBP (Butylbenzylphthalate). For Coloplast the products presented in this list will be labeled as indicated below.








It is recommended to consult the list **“Alternatives to Coloplast products containing classified phthalates”**

Products	Product Codes / Catalogue Number	Content of phthalate and required label
<b>Ostomy Care</b>		
Irrigation set	015110	 DEHP
<b>Wound &amp; Skin Care</b>		
No products in this product area contain classified phthalates		
<b>Consumer Products</b>		
No products in this product area contain classified phthalates		
<b>Urology &amp; Continence Care</b>		
EasiCath Set /SureCath Set	280300, 280260, 280270, 280280, 280290, 280020, 280060, 280130, 280160, 280030, 280070, 280170, 280040, 280080, 280180, 280090, 280190, 280100, 280200, 280110, 280010, 280050, 28005S, 28006S, 28007S, 28008S, 28009S, 28022S, 28023S, 28024S, 28025S, 28026S, 280260, 270270, 28027S, 280280, 28028S, 280290, 280300, 28032S, 28033S, 28036S, 28037S, 280320, 280330, 280360, 280370, 28003S, 28004S, 280140, 28011S, 280120,	 DEHP DBP  <i>Concentration of DBP below 0.1%</i>
EasiCath	053485, 053487, 053488, 053500, 053504, 053505, 053507, 053508, 053525, 053527, 053528, 053543, 053544, 053545, 053547, 053548, 053563, 053565, 053567, 053568, 053583, 053585, 053587, 053588, 053602, 053603, 053605, 053608, 053622, 053623, 053625, 053628, 052880, 052885, 052900, 052905, 052920, 052925, 052940, 052945, 052960, 052965, 052680, 052685, 052700, 052705, 052720, 052725, 052740, 052745, 052760 053665, 053685, 053687, 053688,	 DEHP DBP  <i>Concentration of DBP below 0.1%</i>














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EasiCath	053700, 053704, 053705, 053707, 053708, 053725, 053727, 053728, 053744, 053745, 053747, 053748, 053765, 053767, 053768, 053805, 053808, 053825, 053828, 053845, 053848, 053865, 053868, 053885, 053888, 050067, 050068, 050080, 050087, 050088, 050100, 050107, 050108, 050865, 050885, 050900, 050905, 053800, 050920, 053720, 053724, 053520, 053524, 053820, 053740, 053540, 053840, 053760, 053560, 053860, 053580, 053880, 053600, 053620, 050860, 050868, 050888, 050900, 050905, 050908, 050920, 050928, 050060, 050880, 050885, 053680, 053480, 050080, 283160, 283165, 283180, 283185	 DEHP DBP  Concentration of DBP below 0.1%
Conveen catheter	T20181, T20162, T20142, T20122, T20161, T20141, T20121, T20182, 05304N, 05306N, 05308N, T30102, T30082, T30062, T30061, T30081, T30101, 05009N, 05320N, 05322N, 05324N, 05326N, 05328N, T10101, T10121, T10141, T10161, T10181, T10182, T10162, T10142, T10122, T10102, 05310N, 05312N, 05314N, 05316N, 05318N,	 DEHP
Drainage Bag	1012, 1030	 DEHP
Conveen Standard Urine bag	05620, 05621, 05622, 05623, 050626, 050630	 DEHP
Coveen Contour and Basic Urinebag	051788, 051851	 DEHP
Conveen / Simpla Urine Bag (Leg-bags and Bedside drainage Bags)	050500, 050620, 051700, 051702, 051710, 051720, 051730, 051740, 051744, 051750, 051760, 051762, 051770, 051771, 051780, 051981, 051991, 210660, 051851, 051851, 210380, 210390, 210410, 210430, 210440, 210450, 210470, 210500, 210620, 210621, 210630, 210631, 051961, 210640, 051881, 210650, 210651, 051921, 210670, 210673, 210680, 210720 210800, 212010, 212620	 DEHP
Simpla trident and stand urine bag (leg-bags and bedside drainage bags)	311101, 320904, 32110, 33110, 33111, 33112, 340802, 340805, 34081, 34614, 350600, 370802, 370807, 370809, 370817, 370819, 370893, 370895, 370897, 370899, 370901, 370903, 370904, 370927, 370928, 370929, 370930, 376137, 376138, 376139, 376140, 376141, 376142,	 DEHP










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Products	Product Codes / Catalogue Number	Content of phthalate and required label
Simpla Profile Hospital Bedside Drainage Bag	215560	
Uriflex (irrigation)	GR026, GR027, GR056, GR066, GR076, GR086, GA626	
Freedom Classic (leg-bag and Bed-side Drainage bag)	508120, 508130, 508140, 508220, 508230, 508240, 508250, 558310, 558320, 558330, 508600, 508610, 508650, 508660, 508700, 508710, 508750, 508760, 508400, 508410, 508420, 508430, 508790, 508100, 508110, 508210, 553500, 553510, 553520, 553530, 5535301, 553490, 554300, 553650, 553700, 553750, 553800, 553850, 553860, 553110, 553170, 516410, 553190, 553600, 553180, 553500, 553510, 553520, 553530, 553550, 553560, 553570, 28-07078, 28-07079, 28-07086, 28-07089,	
Freedom leg-bag Triform Bedside Drainage Bag	TF500X, TF500S, TF500M, TF500L, TF750M, PE1550, 515800, 515810, 515820, 515830, 515900, 515910, 515920, 515930, 515950, 515970, 515980, 516000, 516010, 516020, 516030, 516040, 516200, 516210, 516220, 516230, 516250, 516270, 516280, 516290, 553310, 553320, 553410, 553430, 553450, 553470, 522830, 522840,	
Self-Cath Closed system	502600, 502610, 502620, 502630, 502640, 502700, 502710, 502720, 502730, 502740, 502770, 502900, 502850, 502960, 502810, 502930, 502860, 502870, 502970, 502980, 502800	
Self-Cath	501960, 502010, 502020, 502030, 502040, 502300, 502310, 502320, 502330, 504000, 504010, 504020, 504030, 502460, 502480, 504600, 504610, 504620, 504630, 503500, 503510, 502200, 502210, 504500, 504510, 504520, 504530, 504540, 504550, 504580, 504700, 504710, 504720, 504730, 504740, 504750, 504760, 505100, 504400, 504410, 504420, 504430, 504650, 504660, 504670, 504680, 505080, 509480, 509700, 513410, 513420, 513430, 513440, 513450, 516500, 516510, 517100, 517110, 517120, 517130	
Self-Cath plus	505110, 505120, 505130, 505020, 505030, 505040, 523110, 523120, 523130, 523140, 523150, 504900, 504910, 504920, 504930, 504940, 504950, 523010, 523020, 523030,	

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Products	Product Codes / Catalogue Number	Content of phthalate and required label
	523040, 523050, 505200, 505210, 505220, 505230, 505240, 505250, 504800, 504810, 504820,	
Self-Cath HydroGel single	520110, 520120, 520130, 520140	
Self-Cath HydroGel kit	503650, 503651, 503660, 503661, 503670, 503671, 503680, 503681, 503690 503691	
Self-Cath Soft	501800, 501810, 501820, 501830, 503000, 503010, 503020, 503030, 27058,	
Self-Cath Accessories	507850	
Extension tubes and other accessories	380303, 380PP2, 500510, 500520, 505110, 508350, ET3000, ET6000	
Ronocath	RC10F0, RC12F0, RC14F0, RC16F0, RC10M0, RC12M0, RC14M0, RC16M0, RC08P0	
Resurine and other urine bags	PE1000, PE1031, PE1120, PE1420, PE1430, PE8000, PX0500, PX2000,	
CystoCare Urine bags	503700, 503710, 503720, 503721, 503730, 509420, 558510, 558520, 501700, 516460, 516470, 558530, 555200, 558400, 513300, 555210, 558450, 516450, 516460, IB2000, IB2000C	
CystoCare Drain bag	UB0400, UB0450, UB0500	
CystoCare Leg bag	UB0600, UB0950	
CystoCare Urine Meter	UB6000	
CystoCare Intermittent Catheter	FC1014, NC1006, NC1008, NC1010, NC1012, NC1014, NC1016, NC1018, NC1020, NC1022, 558550, CF1012, CF1014, CM1012, CM1014, CM1016,	
CystoCare Closed System	CS1120, CS1140, CS1160, CS0120, CS0140, CS0160,	

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Products	Product Codes / Catalogue Number	Content of phthalate and required label
Cystodrain supra-pubic drainage set with urine bag	AJ7512, AJ7515	
Luerlock	052680, 052685, 052700, 052880, 052885, 052900	
Uncoated Intermittende catheters	5304, 5305, 5308, 5310, 5318, 5312, 5314, 5316, 5320, 5322, 5324, 5326, 5009, 281600, 28610, 28620, 509330, 509340, 509350, KM2508, KM2810, T20181, UC1008, UC1010, UC1012, UC6012, UC6014, UC6016, UC6018, UC6020, UC6022	
UroCath	B02306, B02308, B02310, B02312, B02314, B02316, B02318, H02306, H02308, H02310, H02312, H02314, H02316, H02318, B02408, B02410, B02412, B02414, B02416, H02408, H02410, H02412, H02414, H02416, B02508, B02510, B02512, B02514, B02516, B02518, B02520, H02508, H02510, H02512, H02514, H02516, H02518, H02520, H02818, H02816, H02814, H02812, H02810, H02808, B02818, B02816, B02814, B02812, B02808, B02810, H02112, H02110, H02116, H02114, 530000, 530010, 530020, 530030, 530100, 530110, 530120, 530130, 530200, 530210, 530220, 530230,	
UroCath gel	K02306, K02308, K02310, K02312, K02314, K02316, KM2510, KM2512, KM2514, KM2516, KM2812, KM2814, KM2816, K02506, K02508, K02510, K02512, K02514, K02516, K02518, K02810, K02812, K02814, K02816, K02818, KM2306, KM2310, KM2312, KM2314, KM2316, K03001	
Miscellaneous	RJD108, RJD110	
Suprapubic drainage	AJ8609, AJ8709,	
Wound drainage	GA7108, GA7110, GA7112, GA7114, GA7116, GA7118, GA7120, GA7122, GA7124, GA7126, GA7128, GA7130, GA7132, GA7134, GA7135, GA7140	
Peristeen Anal Irrigation (PAI)	291210, 291220, 291230, 291260, 291270, 291280	

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Products	Product Codes / Catalogue Number	Content of phthalate and required label
		<i>Concentration of DBP below 0.1%</i>
Urisheaths and urine bags	PA4325, PA4330, PA4335, PA5125, PA5130, PA5132, PA5135, PA5140, 051820, 051830, 051840, 052820, 052830, 052840, 210700, 210710, 217410, 217420, 217430, 217440, 217500, 217510, 217520, 217530,	