INFORMATION ON USA AND EUROPEAN COSMETIC REGULATIONS

One of the complexities of complying with cosmetic regulations are the differences between the USA and Europe. There are many instances where what is allowed in USA is not allowed in Europe and vice-versa. There are also differences between the descriptions of the applications.

In the USA there are considerably less colours allowed, as compared to Europe. Below is a summary of FDA regulations and a comparison with the EU Cosmetic Directive. There is also additional information including restrictions in applications.

The summary is split into two sections. In the first section, the dyes and pigment shown are those that FastColours can offer that are batch exempt for usage in USA.

In the second section, it lists all those dyes and pigments that are allowed to be used in cosmetics in USA with batch certification.

Those with highlighted names, FastColours are able to offer as colours that are batch certified by FDA.

Application Areas

USA		Europe	
Application 1	Coloring cosmetics generally	Application 1	All
Application 2	Externally applied cosmetics	Application 2	Eyes (not allowed)
Application 3	Use in the area of the eye	Application 3	Mucous membranes (not allowed)
Application 4	Mouthwashes and dentifrices	Application 4	Cosmetic products except for eyes & mucous membranes
Application 5	Lips		

Additional Uses & Info.

D&C Black No 2	Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel
D&C Black No 3	Eyeliner, eye shadow, mascara, and face powder
D&C Green No 8	Not exceeding 0.01 percent by weight of the finished cosmetic product
D&C Orange No 5	For intended lip products, amounts not to exceed 5.0% by weight of the finished cosmetic products
D&C Red No 33	For intended lip products, amounts not to exceed 3.0% by weight of the finished cosmetic products
D&C Red No 36	For intended lip products, amounts not to exceed 3.0% by weight of the finished cosmetic products
D&C Yellow No 10	Although the EU and USA product have the same CI number, they are not interchangeable as the specifications are different

Batch Certification Exempt

USA Name	CI Index Name	INCI Name	US App. 1	US App. 2	US App. 3	US App. 4	US App. 5	US Additional Uses & Info	Allowed in EU	EU App. 1	EU App. 2	EU App. 3	EU App. 4
Annatto	Natural Orange 4	75120	;		;				;	;			
Caramel	Natural Brown 10	Caramel	;		;				;	;			
Carmine	Natural Red 4	75470	;		;				;	;			
Beta Carotene	Food Orange 5	40800	;		;				;	;			
Iron Oxide Yellow	Pigment Yellow 42	77492	;		;				;	;			
Iron Oxide Red	Pigment Red 101	77491	;		;				;	;			
Iron Oxides Black	Pigment Black 11	77499	;		;				;	;			
Iron Oxides Brown	Pigment Red 101 Pigment Yellow 42 Pigment Black 11	77491 77492 77499	;		;				;	;			
Chromium Oxide Green	Pigment Green 17	77288		;	;				;	;			
Titanium Dioxide	Pigment White 6	77891	;		;				;	;			
Ultramarine Blue	Pigment Blue 29	77007		;	;				;	;			
Ultramarine Violet	Pigment Violet 15	77007		;	;				;	;			

Batch Certification Required

USA Name	CI Index Name	INCI Name	US App. 1	US App. 2	US App. 3	US App. 4	US App. 5	US Additional Uses & Info	Allowed in Europe	EU App. 1	EU App. 2	EU App. 3	EU App. 4
D&C Black No 2	Pigment Black 6	77266					;	See Below	;	;			
D&C Black No 3	Pigment Black 9	77267						See Below	;	;			
FD&C Blue No 1	Food Blue 2	42090	;		;				;	;			
FD&C Blue No 1 Lake	Food Blue 2:1	42090:1	;		;				;	;			
D&C Blue No 4	Acid Blue 9	42090		;									
D&C Brown No 1	Acid Orange 24	20170		;									
FD&C Green No 3	Food Green 3	42053	;						;	;			
D&C Green No 5	Acid Green 25	61570	;		;				;	;			
D&C Green No 6	Solvent Green 3	61565		;					;	;			
D&C Green No 8	Solvent Green 7	59040		;				See Below	;				;
D&C Orange No 4	Acid Orange 7	15510		;					;			;	;
D&C Orange No 5	Acid Orange 11	45370		;		;	;	See below	;	;			
D&C Orange No 10	Acid Red 95	45425		;									
D&C Orange No 11	Acid Red 95	45425		;									
FD&C Red No 4	Food Red 1	14700		;					;	;			
D&C Red No 6	Pigment Red 57:2	15850:2	;						;	;			
D&C Red No 7	Pigment Red 57:1	15850:1	;						;	;			
D&C Red No 17	Solvent Red 23	26100		;					;				;
D&C Red No 21	Solvent Red 43	45380:2	;						;	;			
D&C Red No 27	Solvent Red 48	45410:1	;						;	;			
D&C Red No 27 Aluminium Lake	Pigment Red 174	45410:2	;						;	;			
D&C Red No 28	Acid Red 92	45410	;						;	;			
D&C Red No 30	Pigment Red 181	73360	;						;	;			
D&C Red No 31	Pigment Red 64	15800		;					;				;
D&C Red No 33	Acid Red 33	17200		;		;	;		;	;			
D&C Red No 34	Pigment Red 63	15880		;					;	;			
D&C Red No 36	Pigment Red 64	12085		;			;	see below	;	;			
FD&C Red No 40	Food Red 17	16035	;		;				;	;			
FD&C Red No 40 Lake	Food Red 17:1	16035:1	;		;				;	;			
D&C Violet No 2	Solvent Violet 13	60725		;					;	;			
Ext D&C Violet No 2	Acid Violet 43	60730		;					;				;
FD&C Yellow No 5	Food Yellow 4	19140	;		;				;	;			
FD&C Yellow No 5 Lake	Food Yellow 4:1	19140:1	;		;				;	;			
FD&C Yellow No 6	Food Yellow 3	15985	;		;				;	;			
FD&C Yellow No 6 Lake	Food Yellow 3:1	15985:1	;		;				;	;			
D&C Yellow No 7	No CI Name			;									
Ext D&C Yellow No 7	Acid Yellow 1	10316		;					;			;	;
D&C Yellow No 8	Acid Yellow 73	45350		;					;	;			
D&C Yellow No 10	Food Yellow 13	47005		;				see below	;	;			
D&C Yellow No 11	Solvent Yellow 33	47000		;					;				;

Please call the company if you require additional help.

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