

DBCaps® Capsules Daily Intakes for Colorants

The information provided below is for guidance purposes only. As regulatory rulings of various countries are constantly open to review and change, Capsugel suggests that decisions regarding daily intake limits be made with review by appropriate Regulatory experts.



The World Health Organization (WHO), the US Code of Federal Regulations (CFR), and the Japanese Pharmaceutical Excipients Directory (JPED) have set guidelines on ingestion of Iron Oxide and Elemental Iron. Iron Oxides are commonly used in pharmaceutical grade colorants.

WHO	0.5 mg /day / kg of iron oxide (calculations based on standard human weight of 60 kg)
CFR	5 mg /day of elemental iron (calculations based on 70% iron content of iron oxide colorants)
JPED	95.4 mg/day of red iron oxide; 5.67 mg/day of yellow iron oxide*; 1.539 mg/day of black iron oxide

For each DBCaps® capsule size, the tables below indicate the approximate maximum number of DBCaps capsules that are within these limits set by global regulatory agencies.

Color	Color Code			Daily Maximum		
	US	EMA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	15	3	3
Gray Opaque	3979	11.300	07.505	48	11	2
Swedish Orange Opaque	4188	22.307	32.515	17	2	56
Yellow Opaque	8072	42.335	51.537	23	5	4

Color	Color Code			Daily Maximum		
	US	EMA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	17	4	4
Gray Opaque	3979	11.300	07.505	57	13	2
Swedish Orange Opaque	4188	22.307	32.515	14	3	47
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	27	7	5

Color	Color Code			Daily Maximum		
	US	EMA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	22	5	5
Gray Opaque	3979	11.300	07.505	70	16	3
Swedish Orange Opaque	4188	22.307	32.515	18	4	58
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	34	9	6

*Yellow iron oxide is defined by JPED as Yellow Ferric oxide.

SIZE A

Color	Color Code			Daily Maximum		
	US	EMEA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	26	6	6
Gray Opaque	3979	11.300	07.505	85	19	4
Swedish Orange Opaque	4188	22.307	32.515	22	5	70
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	41	11	7

SIZE B

Color	Color Code			Daily Maximum		
	US	EMEA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	37	9	8
Gray Opaque	3979	11.300	07.505	118	27	6
Swedish Orange Opaque	4188	22.307	32.515	30	7	98
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	58	15	10

SIZE C

Color	Color Code			Daily Maximum		
	US	EMEA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	42	10	10
Gray Opaque	3979	11.300	07.505	135	31	7
Swedish Orange Opaque	4188	22.307	32.515	35	8	112
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	66	17	12

SIZE D

Color	Color Code			Daily Maximum		
	US	EMEA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	51	13	12
Gray Opaque	3979	11.300	07.505	165	38	8
Swedish Orange Opaque	4188	22.307	32.515	43	10	136
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	80	21	15

SIZE E

Color	Color Code			Daily Maximum		
	US	EMEA	JPN	WHO	CFR	JPED
Caramel Opaque	5782	36.304	86.507	64	16	15
Gray Opaque	3979	11.300	07.505	207	47	10
Swedish Orange Opaque	4188	22.307	32.515	54	9	171
White Opaque	8990	44.313	02.561/02.568	N/A	N/A	N/A
Yellow Opaque	8072	42.335	51.537	101	26	19

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