

DBcaps® 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.

SIZE AAA

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Swedish Orange Opaque (4188)	17	2	56
Swedish Orange Opaque (7274)†	23	3	75
Yellow Opaque (8072)	23	5	4
Gray Opaque (3979)	48	11	2
Carmel Opaque (5782)	15	3	3

SIZE AA el

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	17	4	4
Swedish Orange Opaque	14	3	47
Gray Opaque	57	13	2
Yellow Opaque	27	7	5
White Opaque (8990)	No limit	No limit	No limit

SIZE AA

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	22	5	5
Swedish Orange Opaque	18	4	58
Gray Opaque	70	16	3
Yellow Opaque	34	9	6
White Opaque	No limit	No limit	No limit

†Custom Color for AAA size, all other sizes use color 4188.

SIZE A

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	26	6	6
Swedish Orange Opaque	22	5	70
Gray Opaque	85	19	4
Yellow Opaque	41	11	7
White Opaque	No limit	No limit	No limit

SIZE B

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	37	9	8
Swedish Orange Opaque	30	7	98
Gray Opaque	118	27	6
Yellow Opaque	58	15	10
White Opaque	No limit	No limit	No limit

SIZE C

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	42	10	10
Swedish Orange Opaque	35	8	112
Gray Opaque	135	31	7
Yellow Opaque	66	17	12
White Opaque	No limit	No limit	No limit

SIZE D

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	51	13	12
Swedish Orange Opaque	43	10	136
Gray Opaque	165	38	8
Yellow Opaque	80	21	15
White Opaque	No limit	No limit	No limit

SIZE E

Maximum Number of Capsules/Day to Meet Regulatory Limits

Color	WHO	CFR	JPED
Carmel Opaque	64	16	15
Swedish Orange Opaque	54	9	171
Gray Opaque	207	47	10
Yellow Opaque	101	26	19
White Opaque	No limit	No limit	No limit



For more information on DBcaps visit capsugel.com or contact your sales representative.

Literature Code: 200903002

CAPSUGEL[®]
Quality
People and Products Working Together[™]