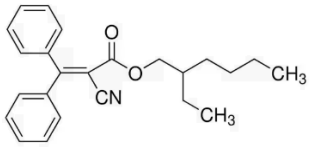
FACTSHEET Octocrylene (OC)	Update[1] of the derivation of HBM values 		
Substance	**Octocrylene**		
Year of value derivation	**2023**		
Update	**2026**		
Underlying publication	**Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz 66** **https://doi.org/10.1007/s00103-023-03785-2 [1]**		
Parameters	**Value / Descriptor**	**Dimension**	**Comment**
HBM values CPAA			
HBM-I value (men/children)	5.3	mg/L	Matrix: urine Biomarker CPAA (2-cyano-3,3-diphenylacrylic acid)
HBM-I value (women)	4.5	mg/L	
HBM-II value (men/children)	18	mg/L	
HBM-II value (women)	16	mg/L	
HBM values DOCCA			
HBM-I value (men/children)	22	µg/L	Matrix: urine Biomarker DOCCA (2-(carboxymethyl) butyl 2-cyano-3,3-diphenylacrylate; Dinor-OC-carboxylic acid)
HBM-I value (women)	19	µg/L	
HBM-II value (men/children)	78	µg/L	
HBM-II value (women)	67	µg/L	
General information			
CAS number	6197-30-4		
IUPAC name	2-ethylhexyl-2-cyano-3,3-diphenylacrylate		
Molar mass Octocrylene	361.48	g/mol	
HBM biomarker of exposure	CPAA DOCCA		Specific metabolites
Molar mass of metabolites	CPAA: 249.27 DOCCA: 363.41	g/mol	
Data base toxicology			
Key study/Author(s) (Year)	Triskelion BV, 2019		[2]
Species	Rat		
Method of application/Type of study	Oral (feed)		OECD guideline 443
Duration of exposure	Extended One-Generation Reproductive Toxicity Study (EOGRTS)		During the mating season (10 weeks) and the mating period (max. 2 weeks), pregnancy and lactation up to the 21st postnatal day
Critical endpoint/Effect	Systemic toxicity, reproductive and developmental toxicity		
NOAEL LOAEL	153 534	mg/kg bw/d	POD for HBM-I values POD for HBM-II values

[1] The HBM values were updated on the basis of updated daily urine volumes normalised for body weight, and by systematically rounding the calculated values.

Assessment factors and external dose for deriving HBM values			
Adjusted exposure factor (time scaling)	2		Any potential amplification of effects due to exposure over lifetime must be taken into account
Interspecies factor	4		Allometric
	2.5		Dynamic
Intraspecies factor	5		General population, kinetic + dynamic; reduced from 10 to 5, as EOGRTS covers the particular sensitivity during development
Other assessment factors: Quality of the data as a whole	3		Taking into account uncertainties relating to the results of the mechanistic study [3]
Total assessment factor (TAF)	300		
POD/TAF	For HBM-I: 0.51 For HBM-II: 1.78	mg/kg bw/d	External tolerable dose (ETD) for the HBM-I value: 153/300 = 0.51 External dose for the HBM-II value: 534/300 = 1.78
Parameters for calculating HBM values using the mass balance approach			
Fue	CPAA: 0.45 DOCCA: 0.0013		Excretion factor, the proportion of the active substance dose excreted in the urine as a specific metabolite, on a molar basis [4,5]
Ratio of the molar mass of the metabolite to the molar mass of octocrylene	For CPAA: 0.69 For DOCCA: 1.01		249.27/362.48 363.41/362.48
Urine volume per kg bw per day	Men/Children: 0.030 Women: 0.035	L/ (kg bw · d)	Default values [6]
Calculation of HBM values in accordance with the mass balance approach ([7])			
CPAA			
HBM-I value (men/children)	Calculated value: 5.28 Rounded value: 5.3	mg/L	[0.51×0.69×0.45] /0.030
HBM-I value (women)	Calculated value: 4.52 Rounded value: 4.5	mg/L	[0.51×0.69×0.45] /0.035
HBM-II value (men/children)	Calculated value: 18.4 Rounded value: 18	mg/L	[1.78×0.69×0.45] /0.030
HBM-II value (women)	Calculated value: 15,8 Rouded value: 16	mg/L	[1.78×0.69×0.45] /0.035
DOCCA			
HBM-I value (men/children)	Calculated value: 0.0223 Rounded value: 0.022 (≙ 22 µg/L)		[0.51×1.01×0.0013] /0.030
HBM-I value (women)	Calculated value: 0.0191 Rounded value: 0.019 (≙ 19 µg/L)		[0.51×1.01×0.0013] /0.035
HBM-II value (men/children)	Calculated value: 0.0779 Rounded value: 0.078 (≙ 78 µg/L)		[1.78×1.01×0.0013] /0.030
HBM-II value (women)	Calculated value: 0.0668 Rounded value: 0.067 (≙ 67 µg/L)		[1.78×1.01×0.0013] /0.035

Reasoning

Octocrylene (OC) is used as a UV filter in sunscreens due to its UV-absorbing properties in the UVB and UVA ranges, usually in combination with other UV filters. Furthermore, due to its photostability, it is used as a stabiliser for other non-photostable UV filters in sunscreens and cosmetics, or as a photostabiliser for other products (e.g. plastics).

The Extended One-Generation Reproductive Toxicity Study (EOGRTS) [2] is regarded as a key study for assessing the toxicity of OC, and the NOAEL (*No Observed Adverse Effect Level*) of 153 mg/kg body weight per day for systemic, reproductive and developmental toxicity was used as the starting point (POD - *Point Of Departure*) for deriving HBM-I values. The LOAEL (*Lowest Observed Adverse Effect Level*) from the EOGRTS, amounting to 534 mg/kg bw/day, served as the basis for deriving HBM-II values. A mechanistic subacute feeding study in Wistar rats [3] was used as supporting study.

Taking into account an overall assessment factor of 300, a TDI-equivalent value (TDI: *Tolerable Daily Intake*) of 0.51 mg/kg bw/day was calculated based on the NOAEL to derive the HBM-I values, and an external dose of 1.78 mg/kg bw/day was calculated to derive the HBM-II values.

The OC metabolites CPAA (ester hydrolysis product 2-cyano-3,3-diphenylacrylic acid) with a Fue of 45 % and DOCCA (beta-oxidation product 2-(carboxymethyl)butyl 2-cyano-3,3-diphenyl acrylate (dinor-OC-carboxylic acid)) with a Fue of 0.13 % are the exposure biomarkers relevant to human biomonitoring [4,5].

Based on the PODs and assessment factors set out above, HBM-I and HBM-II values were derived and agreed upon separately for the biomarkers CPAA and DOCCA.

For the **CPAA biomarker**, HBM-I values of 5.3 mg/L were derived for children and men, and 4.5 mg/L for women. The HBM-II value is 18 mg/L for children and men, and 16 mg/L for women.

For the **DOCCA biomarker**, the HBM-I values are 22 µg/L for children and men, and 19 µg/L for women. The HBM-II value is 78 µg/L for children and men, and 67 µg/L for women.

References

1. Kommission Human-Biomonitoring des Umweltbundesamtes (2023) Stoffmonographie für Octocrylen – HBM-Werte für die Metaboliten 2-Cyano-3,3-diphenylacrylsäure (CPAA) und 2-(Carboxymethyl)butyl 2-cyano-3,3-diphenylacrylat (Dinor-OC-Carbonsäure, DOCCA) im Urin der Allgemeinbevölkerung. Bundesgesundheitsbl 66: 1304–1314. https://doi.org/10.1007/s00103-023-03785-2

2. Triskelion BV (2019) Extended One Generation Reproductive Toxicity Study (EOGRTS) according OECD Test Guideline 443. Testing laboratory: Triskelion BV, Report no: 03R0495/00X056, Owner company: BASF SE; DSM

3. BASF SE (2019) Octocrylene—Mechanistic study in Wistar rats on thyroid toxicity via enzyme induction in the liver. Administration via the diet for 4 weeks (study report). Testing laboratory: BASF SE, Report no: 99C0495/00S048. Owner company; BASF SE; DSM Nutritional Products AG; Merck KGaA; Symrise AG

4. Bury D, Belov VN, Qi Y, Hayen H, Volmer DA, Brüning T, Koch HM (2018) Determination of urinary metabolites of the emerging UV filter octocrylene by online-SPE-LC-MS/MS. Anal Chem 90(1): 944–951. https://doi.org/10.1021/acs.analchem.7b03996

5. Bury et al (2019) Urinary metabolites of the UV filter octocrylene in humans as biomarkers of exposure. Arch Toxicol 93(5): 1227–1238

6. Kommission Human-Biomonitoring des Umweltbundesamtes (2025) Änderung des Leitwertes für die körpergewichtsnormierte tägliche Urinausscheidung von Erwachsenen. *Bundesgesundheitsbl* 68: 830–837. https://doi.org/10.1007/s00103-025-04062-0

7. Kommission Human-Biomonitoring des Umweltbundesamtes (2014) Grundsatzpapier zur Ableitung von HBM-Werten. Stellungnahme der Kommission Human-Biomonitoring des Umweltbundesamtes. Bundesgesundheitsbl Gesundheitsforsch Gesundheitsschutz 57(1):138-147. http://link.springer.com/article/10.1007/s00103-013-1867-2