

Statement

Product Purity Profile

Eumulgin® CO 40

PRD 30570063

Valid since 15.09.2023
Revision 1.1

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The presence of traces of the below declared substances stemming from raw materials used and/or being formed in the manufacturing process of the product, is not intended and is technically unavoidable. In accordance with Article 17 of the Cosmetics Regulation (EC) 1223/2009 such traces of prohibited substances are accepted.

Substance	Description / Status	Limits
1,4-Dioxane	Is present:	max. 10 ppm
Aflatoxin/Mycotoxin	Based on information concerning the raw materials, production process, and equipment used Aflatoxin/ Mycotoxin are expected to conform with the concentration limits of Regulation (EC) 1881/2006 Annex, Section 2.1.5	Aflatoxins B1: max. 2.0 µg/kg Sum of Aflatoxins B1, B2, G1 and G2: max. 4.0 µg/kg
CMR substances	May contain the following CMR substances:	1,4-Dioxane: max. 10 ppm Ethylene oxide: max. 1 ppm
Diethylene glycol	Sum of ethylene glycol and diethylene glycol	max. 0.1 %
Food allergens	Based on information concerning the raw materials, production process, and equipment used food allergens as of EU Directive 2000/13/EC (as amended), Annex IIIa, and Regulation (EU) 1169/2011, Annex II are not likely to be present.	
Fragrance allergens	Based on information concerning the raw materials, production process, and equipment used fragrance allergens as of EU Regulation 1223/2009 Annex III are not likely to be present.	
Glycol ethers	Based on information concerning the raw materials, production process, and equipment used the following glycol ethers are not likely to be present: Butyldiglycol (CAS No 112-34-5) Ethylidiglycol (CAS No 111-90-0) 2-Butoxyethanol (CAS No 111-76-2)	
Heavy metals	Refer to statement Heavy Metals	
Heavy metals	Heavy metals in sum (as Pb):	< 10 ppm according to the Ph. Eur.2.4.8. (antimony, arsenic, lead, bismuth, cadmium, copper, mercury and tin)

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Other impurities	Is present:	Ethylene glycol: max. 620 ppm Acetic acid: max. 0.5 %
Pesticides	Based on information concerning the raw materials, production process, and equipment used, pesticides are expected to conform with concentration limits of the European Pharmacopoeia; Section 2.8.13 "Pesticide residues", Table 2.8.13.-1	
Phthalates	Based on information concerning the raw materials, production process, and equipment used phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.	
Polycyclic aromatic hydrocarbons	Based on information concerning the raw materials, production process, and equipment used, polycyclic aromatic hydrocarbons are not likely to be present.	
Proposition 65	Refer to statement Declaration California Proposition 65	
Residual monomers	The following residual monomers may be present	Ethylene oxide: max. 1 ppm
Residual solvents	The following residual solvents may be present	Acetic acid: max. 0.5 % Diethylene Glycol: max. 0.1 % Ethylene Glycol: max. 620 ppm

- "Not likely to be present" means: The substance(s) is/are not used as a raw material and are not known to be formed during the manufacturing process and therefore not tested for.
- "Not likely to be present due to the process" means: The substance(s) is/are an unavoidable impurity either present from the raw materials or formed during the manufacturing process. However due to the nature of the manufacturing process, the particular substance is not expected to be present in declarable amounts and therefore not tested for.
- When a value is indicated: The substance(s) is/are either used as a raw material or known to be formed during the manufacturing process and which cannot be completely removed and present at the indicated level. When levels are indicated then values are as expected immediately after production and not necessarily after prolonged storage and/or transport.
- "Compliance is monitored" means: The substances itself or representative material is monitored at intervals for compliance with the listed Guideline and/or the raw material grade used is of an appropriate purity to satisfy the requirements.
- Note: Only substances which are intentionally added or known to be formed are scope of the BASF product documentation. The potential presence or absence of non-documented substances are excluded from any form of testing or monitoring if not suspected to be present.



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