	Dossier technique et réglementaire / <i>technical and regulatory document</i> CIRE HCO - BUTETH	Février 2025 / <i>February 2025</i>
--	---	--

INCI	%	N°CAS	N°EINECS/ELINCS
PEG-40 hydrogenated castor oil	25 – 50 %	61788-85-0	Polymer
PPG-26-Buteth-26	50 - 75 %	9038-95-3*	Polymer
Aqua	5 – 10 %	7732-18-5	231-791-2

*Generic CAS

DESCRIPTION / DESCRIPTION:

Mélange d'alcool gras éthoxylés/propoxylés et de dérivés végétaux / *Blend of fatty alcohol ethoxylated/propoxylated and vegetable derivatives*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect / <i>Aspect</i>	Liquide visqueux / <i>viscous liquid</i>	ICP 001
Couleur / <i>Color</i>	Jaune paille / <i>Yellowish</i>	ICP 002
Indice d'acide / <i>Acid number</i>	≤ 1 mg KOH/g	ICP 004
pH (10% dans l'eau) / <i>pH (10% in water)</i>	5.5 – 7	ICP 008
Indice d'iode / <i>Iodine value</i>	≤ 3 gI ₂ /100g	ICP 017

Ces éléments seront repris sur nos BA / *these elements will be on our CoA*

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Soluble dans l'eau / *Soluble in water*

Point éclair / *Flash point*: > 125°C

HLB: 14

ISO 16128 - With formulation water:

NATURAL CONTENT: 5-10%

NATURAL ORIGIN CONTENT: 5-10%

ORGANIC CONTENT: 0%

ORGANIC ORIGIN CONTENT: 0%

Without formulation water:

NATURAL CONTENT: 0%

NATURAL ORIGIN CONTENT: 0%

ORGANIC CONTENT: 0%

ORGANIC ORIGIN CONTENT: 0%

APPLICATIONS:

Solubilisants pour concentrés de parfum, huiles essentielles, vitamines ou autres composants huileux dans le système d'eau / *Solubilizers for perfume concentrates, essential oils, vitamins or other oily components in water system*


CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Tonnelet de 50 kg ouverture totale / *50 kg keg*


Matière première non dangereuse / *Non dangerous raw material*

A stocker à < +30 ° C dans des emballages d'origine fermés et à l'abri de l'humidité. Pendant le stockage à froid, il peut se produire une séparation et une solidification réversibles par chauffage à 50 - 60°C et agitation. Pour l'utilisation de parties d'un conteneur, il est recommandé d'homogénéiser les produits au préalable / *Storage at < +30°C in original sealed containers and protected from moisture. During storage at cold temperature, separation and solidification may occur which are reversible through heating to 50 – 60°C and stirring. For use of parts of a container it is recommended to homogenize the products first*

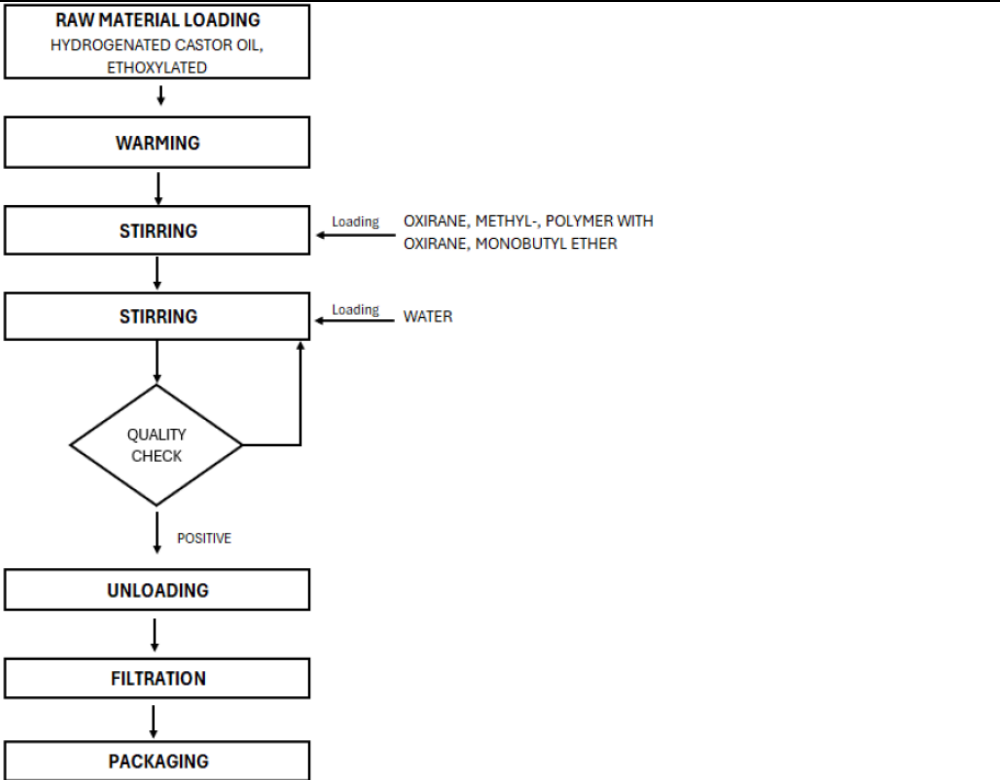
Additives	Antioxidants are not intentionally added and not expected to be present. Formaldehyde and Formaldehyde releasers are not used and not suspected to form during the manufacturing process, not expected to be present in the raw materials used nor
------------------	---

	Dossier technique et réglementaire / <i>technical and regulatory document</i> CIRE HCO - BUTETH	Février 2025 / February 2025
--	---	---------------------------------

	intentionally added to the product, therefore their presence is not expected. Based on starting materials and process of synthesis, formaldehyde is not expected to be present in this ingredient at levels beyond the background levels normally present for this substance, due to its ubiquitous nature (EFSA Journal 2014; 12 (2):3550 [11 pp.].		
Allergen	Allergens listed in the Regulation (EC) 1223/2009 (Annex III) or Regulation (EC) 1169/2011 (Annex II) and its amendments are not used and not suspected to form during the manufacturing process, not expected to be present in the raw materials used nor intentionally added to the product		
Animal Testing	the product has never been tested by the manufacturer on animal nor anybody was Commissioned by manufacturer to test this product on animals.		
BSE - Bovine Spongiform Encephalopathy	The product is not derived from raw material of animal origin and does not contain substances of animal origin, therefore the presence of BSE and TSE is not expected.		
California Prop 65	These products (CAS: 61788-85-0, 9038-95-3 and 7732-18-5) are not listed. But the presence of Ethylene oxide and 1,4-dioxane is not excluded to concentration certainly of order of magnitude well below the limits reported in proposition 65.		
Carcinogenic, Mutagenic and Reprotoxic (CMR)	The product may contain traces of CMR substances, categories 1 A, 1 B or 2 as defined in part 3, Annex VI of Regulation (EC) N°1272/2008 and following amendments, and/or substances listed in Annex II of Cosmetic Regulation (EC) N° 1223/2009 and following amendments.		
	They are technically unavoidable CMR impurities resulting from our qualified manufacturing process (alkoxylation):		
	Chemical name	CAS number	Content
	Ethylene Oxide	(CAS 75-21-8)	< 10 ppm
	Propylene Oxide	(CAS 75-56-9)	< 5 ppm
	1,4 Dioxane	(CAS 123-91-1)	< 10 ppm
	Acetaldehyde	(CAS 75-07-0)	< 50 ppm
	2-Ethoxyethanol	(CAS 110-80-5)	< 5 ppm
	2-Ethoxyethyl acetate	(CAS 111-15-9)	< 5 ppm
	(Standard values; not checked on each product lot)		
Composition	Mixture of PEG-hydrogenated castor oil (25 – 50 %), PPG-26-Buteth-26 (50 - 75%), Aqua (5 – 10 %)		
Cosmetic	This product is in compliance with EC REGULATION No. 1223/2009.		
Cosmos / Ecocert	No data available		
Danger	This mixture is not classified as dangerous in accordance with CLP and ADR		
Dioxane	This mixture contains dioxane (max 10 ppm) and ethylene oxide (max 10 ppm)		
Ecolabel	No data available		
European Pharmacopeia	No data available		
Food	Regulation (EU) No 10/2011 and amendments on plastic materials and articles that come into contact with food: The product is a mixture. At best of our knowledge, not all the constituent substances of the product are listed in the Regulation. Please note that manufacturer has no obligation or liability for determining whether the products and the information in this document are appropriate for customer’s use. It is the responsibility of the end-use manufacturer to verify the compliance of the finished materials or articles at the specific real and/or foreseeable conditions of use, based on the information provided.		
Genetically Modified	The product is not manufactured from genetic resources and, based on our actual		

	Dossier technique et réglementaire / <i>technical and regulatory document</i> CIRE HCO - BUTETH	Février 2025 / February 2025
--	---	---------------------------------

Organisms (GMO)	knowledge, is free from GMO
Inventories	The product is a mixture. All the constituent substances are listed together into the following international Chemical Inventories: EINECS (EU): all listed ENCS (Japan): all listed TSCA (USA): all listed TCSI (Taiwan): all listed DSL (Canada): all listed NZIoC (New Zeland): all listed AIIC (Australia): all listed PICCS (Philippine): all listed IECSC (China): all listed KECI (Korea): all listed
Geographic origin (for plant)	<i>No data available</i>
Glycol ether	<i>No data available</i>
Halal	The product or raw materials are not of animal origin; the product or raw materials have not been in contact with animal products; the product or its raw materials did not originate in the milk; the product or raw materials have not been in contact with sources of dairy origin; the product or its raw materials did not originate from ethanol; the product or raw materials have not been in contact with ethanol or derived from grapes; the product complies with the HALAL precepts.
Heavy Metals	Elemental Impurities according to ICH 3QD are not used in the manufacturing process, not expected to be present in the raw materials used nor intentionally added to the product therefore their presence is not expected. Total heavy metals content: < 10 ppm The accidental presence of Heavy Metals in the product is always below the ETAD (the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) limits. Such limits are internationally recognized as (eco) toxicological threshold values.
HS code	34029010
Irradiation / ionization	The product hasn't been treated with ionizing radiations.
Kosher	<i>No data available</i>
Latex	not intentionally added and not expected to be present.
Manufacturing location	Italy
Microbiological data	Due to the low water content ($\leq 10\%$), the product is not checked for microbiological contamination. At best of our knowledge the product is thus not microbiologically contaminated nor contaminable.
Microplastic	Being liquid, the product doesn't fall under the definition of synthetic polymer microparticles set in the Commission Regulation (EU) 2023/2055. We further confirm that, at best of our knowledge, the product doesn't contain synthetic polymer microparticles as defined in the Commission Regulation (EU) 2023/2055.
Nanomaterials	The product is not considered a nanomaterial and doesn't contain nanomaterials following the definition described in Art. 2 (K) and Art. 16 of Cosmetic Regulation EC 1223/2009 and French decree (2012-232).
Nitrosamines	Not used and not suspected to form during the manufacturing process, not expected to be present in the raw materials used nor intentionally added to the product.
Nutritional data	<i>No data available</i>
Origin	The product is a mixture obtained from raw materials of vegetable, synthetic, petrochemical and natural origin. Vegetable source is from Castor Oil. Vegetable derivation is about 13%.
PAH/PFAS	Polycyclic aromatic hydrocarbons (PAH) not intentionally added and not expected to be present. PFAS (Per- and polyfluoroalkyl substances), as per list included in UE Directive n. 2020/2184, ANNEX III, Part B, Paragraph 3, are not intentionally added and not expected to be present.
Pesticide	Pesticides are not expected to be present in this mixture
Phthalate	Phthalates are not expected to be present in this mixture
Preservative	Preservatives are not expected to be present in this mixture

Process	 <pre> graph TD A[RAW MATERIAL LOADING HYDROGENATED CASTOR OIL, ETHOXYLATED] --> B[WARMING] B --> C[STIRRING] D[Loading OXIRANE, METHYL-, POLYMER WITH OXIRANE, MONOBUTYL ETHER] --> C C --> E[STIRRING] F[Loading WATER] --> E E --> G{QUALITY CHECK} G -- POSITIVE --> H[UNLOADING] H --> I[FILTRATION] I --> J[PACKAGING] </pre>
REACH	These products (CAS: 61788-85-0) and (CAS: 9038-95-3) are polymers according to REACH definition (Article 3, Part 5) – exempted from registration according to Article 2, Part 9 of the regulation itself. We confirm monomers are in compliance with REACH Regulation.
Residual Solvents	Solvents are not expected in this mixture
RSPO	This product doesn't contain palm – not concerned
Shelf Life	24 months
Substances of Very High Concern (SVHC)	The product doesn't contain Substances of Very High Concern (SVHC) reported in the Candidate List for authorization in a concentration higher than 0,1% (following most updated version at the date of this statement).
Volatiles organic compounds (VOC)	<p><i>Directive 2004/42/CE on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC</i></p> <p>&</p> <p><i>Directive 2010/75/EU on the limitation of emissions of VOCs in certain industrial activities</i></p> <p>Due to the complexity of the above-mentioned regulations, a statement could only be made if the conditions of use of the product were known.</p> <p>Since we cannot be aware of such conditions, please make your own assessment based on the volatility and/or boiling point listed in Chapter 9 of the product MSDS.</p> <p><i>"Ordinance on the steering charge on volatile organic compounds" of the Swiss Confederation (SR 814.018)</i></p> <p>According to the above-mentioned Ordinance, products are exempted from tax if their content of VOCs (as listed in Annex I of the Ordinance itself) is lower than 3%.</p> <p>To the best of our knowledge, the product doesn't contain > 3% of the substances listed in the Positive List (Annex 1) defined by Swiss Ordinance 814.018.</p> <p><i>European Commission Decision 2014/312/EU establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes.</i></p> <p>The level of VOC and SVOC according to 2014/312/EU is estimated to be lower than 1%.</p>

----- END

Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*