

Regulatory Data Sheet

Manufacturing Site(s)

Saint-Mihiel

Innospec Performance Chemicals
France SAS
BP 19 Z.I. de Han sur Meuse
55300 Saint-Mihiel
France

Identification

INCI Name: Coco-Betaine
INCI Function: Surfactant

Product Grades / Markets

Cosmetic - Manufactured under EFfCI Good Manufacturing Practices

The composition below is given as a guide to aid with the labeling of finished formulations. It does not represent a specification nor a certificate of analysis. Please refer to the Safety Data Sheet (SDS) for any applicable identification numbers.

** Denotes technically unavoidable Impurity under EffCI Good Manufacturing Practices.*

INCI Name for Labeling

Coco-Betaine

Water/aqua

General Composition

	%
Coco-Betaine	29-31
Water/aqua	q.s. to 100
Free Amine*	<0.4
Sodium Chloride	6.5 - 8
Sodium Monochloroacetate*	<0.015

Impurities and by-products

[Note: Any values provided in this section are typically less than the value(s) stated]

The following are substances and/or impurities of known regulatory concern that may or may not be associated with the chemical profile of EMPIGEN® CBET. Note, where present, the substance is technically unavoidable under recognized Good Manufacturing Practices (EffCI-GMP). As part of Good Product Stewardship, Innospec commissions occasional testing to evaluate the presence of substances in this list that are expected to be present or form in EMPIGEN® CBET, the results of which are shown below. However, those values are not specifications are not routinely measured and therefore we cannot guarantee the values declared. They are provided in this section due to possible overlap in multiple jurisdictions and are not intended to be specifications and/or not routinely measured. Refer to ICCR Traces Working Group reports for the treatment of traces in cosmetics.

<i>1,4-Dioxane:</i>	NF (0.5 mg/kg)
<i>Formaldehyde / Formaldehyde releasers:</i>	Not tested and/or expected
<i>Alkyl phenols, ethoxylates, and derivatives:</i>	Not tested and/or expected
<i>Asbestos:</i>	Not tested and/or expected
<i>BHT/BHA:</i>	Not tested and/or expected
<i>Bisphenols:</i>	Not tested and/or expected
<i>Diethylene Glycol:</i>	Not tested and/or expected
<i>Dyestuffs / Color Additives:</i>	Not intentionally added
<i>EDTA, DTPA, NTA and their salts:</i>	Not tested and/or expected
<i>Elemental Impurities:</i>	Refer to Elemental Impurities section of this document
<i>Ethylene Oxide:</i>	Not tested and/or expected
<i>Melamine:</i>	Not tested and/or expected
<i>Mica:</i>	Not tested and/or expected
<i>Mineral oil saturated and/or aromatic hydrocarbons (MOSH/MOAH):</i>	Not tested and/or expected
<i>Nitrosamines:</i>	Apparent Total N-Nitroso compounds (ATNC) Content as NNO: NF (50 ppb)†
<i>Phthalates:</i>	Not tested and/or expected to contain DEHP, DINP, DBP, DNOP, BBP, DIDP, DIBP
<i>Proteins:</i>	Not tested and/or expected
<i>PFAS/PFOA:</i>	Not intentionally added or expected
<i>Cyclosiloxanes:</i>	Not tested and/or expected
<i>Residual Amines:</i>	Not tested and/or expected
<i>Polyaromatic Hydrocarbons (PAH):</i>	Not tested and/or expected

Regulation (EC) No. 1223/2009 on Cosmetic Products

EMPIGEN® CBET and its components are in compliance with Regulation (EC) No. 1223/2009 (and its amendments) on cosmetic products and can be legally marketed under the EU cosmetics regulation. Any technically unavoidable impurities are listed in the table below, if applicable.

Regulated Substances and/or Technically Unavoidable Impurities under Regulation (EC) No. 1223/2009 on Cosmetic Products:

* Denotes technically unavoidable impurities under EFCI Good Manufacturing Practices

Chemical Name	CAS RN	Concentration	Annex / Ref #	Name on List	Additional Comments
1,4-Dioxane*	123-91-1	NF (0.5 mg/kg)	II/343	Dioxane	none
Apparent Total N-Nitroso compounds (ATNC) Content as NNO*†	n/a	NF (50 ppb)	II/410	Nitrosamines	none

CMR [under CLP]: No substances classified as Carcinogenic, Mutagenic or Toxic for Reproduction of Category 1A, 1B, or 2 and Annex VI of the CLP regulation are present in EMPIGEN® CBET at greater than 0.1% under Regulation (EC) 1272/2008 (CLP). Any traces and impurities that are present are technically unavoidable under the conditions of good manufacturing practices.

Residual Solvents: The presence of any Class 1, Class 2, or Class 3 residual solvents per USP <467> and ICH Guideline Q3C is technically unavoidable under the conditions of good manufacturing practices:
1,4-Dioxane (Class 2) NF (0.5 mg/kg)

Microbiological Status / Preservative Declaration

EMPIGEN® CBET is not expected to support microbial growth based on preservative challenge tests and/or product knowledge.

Innospec has not intentionally added any preservatives to EMPIGEN® CBET including, but not limited to:

METHYLISOTHIAZOLINONE (and) METHYLCHLOROISOTHIAZOLINONE

PARABENS

DMDM HYDANTOIN

PHENOXYETHANOL

Synthetic Polymer Microparticles (Microplastics / Microbeads)

EMPIGEN® CBET is not a "microplastic" or "microbead". In this context, "microplastic" or "microbead" is defined as Water insoluble solid plastic particles of 5 mm or less in any dimension or Plastic microbeads that are 5 mm in size, any plastic particle, including different forms such as solid, hollow, amorphous and solubilized, including biodegradable plastics.

EMPIGEN® CBET is not and does not contain intentionally added "microplastics" in accordance with Commission Regulation (EU) 2023/2055 amending Annex XVII of Regulation (EC) No. 1907/2006.

In this context, "microplastics" (or synthetic polymer microparticles) are defined as polymers that are solid and which fulfill both of the following conditions:

(a) are contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles;

(b) at least 1% by weight of the particles referred to in point (a) fulfill either of the following conditions:

(i) all dimensions of the particles are ≤ 5 mm;

(ii) the length of the particles is ≤ 15 mm and their length to diameter ratio is >3 .

Irradiation Status

Irradiation is not used in the manufacturing, processing, or handling of EMPIGEN® CBET.

Nanoparticles / Nanomaterials

The raw material, EMPIGEN® CBET, and its constituents are not considered nanomaterials in accordance with one or more of the following regulations and definitions:

- European regulation 1223/2009:

"Nanomaterial: an insoluble or biopersistent material, intentionally manufactured and characterised by one or more external dimensions or by an internal structure, on the scale from 1 to 100 nm."

- European recommendation 2022/C 229/01:

"'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm."

- The French decree 2012-232:

"Substance in nano-particulate state: a substance intentionally manufactured on the nanometric scale, containing particles, unbound or as an aggregate or as an agglomerate, where a minimum proportion of the particles, in the number size distribution, in the number size distribution, has one or more external dimensions of between 1 nm and 100 nm."

VOC (Volatile Organic Compounds)

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:

The level of VOC in EMPIGEN® CBET according to 2004/42/CE and 1999/13/EC is estimated to be lower than 1%.

Directive 2010/75/EU on the limitation of emissions of VOCs in certain industrial activities:

The level of VOC in EMPIGEN® CBET according to 2010/75/EU is estimated to be lower than 1%.

Ordinance on incentive tax on VOC 814.018 (Switzerland)

The product contains <3% VOC as defined by Swiss Ordinance 814.018.

Allergens

Fragrance Allergens according to Annex III of the EU Cosmetics Regulation (EC) No. 1223/2009 (as amended by Commission Regulation (EU) 2023/1545)

EMPIGEN® CBET is not expected to contain any of the 82 EU allergens as defined in the regulation. Note: All of the 82 EU allergens are not routinely analyzed. Based on knowledge of product chemistry and the manufacturing process, they are not expected to be present or formed.

US Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) & Food Allergy Safety, Treatment, Education, and Research (FASTER) Act

Note: The product is not meant to be used as a direct food additive or ingredient.

EMPIGEN® CBET is in conformity with US Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) & Food Allergy Safety, Treatment, Education, and Research (FASTER) Act. None of the allergens listed in these regulations [Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame in any form] are contained in the product. Note, the presence of any highly refined oils derived from one of the nine major food allergens and any ingredient derived from such highly refined oil are exempted from the act with the exception of sesame oil. The product is not derived from any feedstocks with known gluten concerns (wheat, rice, barley, oats) and therefore is considered gluten free.

Food Allergens According to Regulation (EU) No. 1169/2011

EMPIGEN® CBET is in conformity with Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. None of the allergens listed in this regulation are contained in the product.

[The list of allergens referred to in this statement include the following and any products thereof: Cereals containing Gluten, Crustaceans (shellfish); Eggs; Fish; Peanuts; Soybeans; Milk (including lactose); Tree Nuts: namely almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut and Macadamia nut (Queensland nut); Celery; Mustard; Sesame seeds; Sulfur dioxide and sulfites (at concentrations of more than 10mg/kg or 10mg/L in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers); Lupin; Molluscs (for example clams, oysters, scallops, snails and squid)]

Origin

Feedstock: EMPIGEN® CBET is derived from fatty acid sourced from palm-kernel and/or coconut (cocos nucifera) and synthetic sources.

RSPO Status: Innospec is committed to the sourcing and use of sustainable palm oil and palm-kernel oil and their derivatives. Innospec has been an ordinary member of the Roundtable on Sustainable Palm Oil since 2013. All Innospec manufacturing facilities handling palm based raw materials and/or Innospec products are RSPO mass balance (MB) supply chained certified. The product is available to purchase as standard version (EMPIGEN® CBET) and RSPO Mass balance certified material (EMPIGEN® CBET/MB) on request. All of the information related to EMPIGEN® CBET in this document is applicable to EMPIGEN® CBET/MB.

Supplier's Declaration of Conformity According to ISO 16128-2:2017

The active ingredient(s) in EMPIGEN® CBET contains more than 50% renewable carbons, therefore it meets the ISO 16128:2017-2 standard for natural and organic cosmetic ingredients and products.

Renewable Carbon Index (RCI) %	Natural Index	Natural Origin Index	Organic Index	Organic Origin Index	Category of final ingredient
76	0	0.76	0	0	Derived Natural

GMO Status: EMPIGEN® CBET is not manufactured with any substance with genetically modified organisms (GMO) concerns.

CITES/ Nagoya Protocol: EMPIGEN® CBET is synthetically derived and/or otherwise out of scope of Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). No known components coming from species included in any CITES appendices are used in the manufacture of this product.

EMPIGEN® CBET is out of scope of the Nagoya Protocol. Either the product is made in a non-signatory country or the technology was developed prior to passage of ABS laws. Innospec continues to monitor the regulations to determine whether these rules apply to our products.

Brazilian Biodiversity Law: No materials subject to Brazilian Biodiversity Law No. 13, 123/15 are contained in EMPIGEN® CBET.

Origin (continued...)

- Vegan Status:** EMPIGEN® CBET does not contain any animal or animal by-products including flesh, bones, milk or milk products, eggs or egg products, honey or honey bee products, silk or dyes from insects, fur, leather, wool, or down feathers.
- Halal Status:** Although EMPIGEN® CBET has not been officially certified under Halal or Islamic Council, we believe this product is permitted under Muslim standards.
The product is synthetically produced from materials that do not originate from animals, animal by-products, pork, or enzymes. Innospec does not use ethyl alcohol / alcoholic beverages in the manufacture of EMPIGEN® CBET. The material is produced and stored in a pork and animal free unit.
- BSE/TSE Status:** EMPIGEN® CBET is derived from non-animal sources and animals or animal derived materials are not used in any stage of the manufacturing process. Therefore, it is free of BSE-TSE concerns with respect to origin.
- Pesticide Residues:**
EMPIGEN® CBET is not a plant extract. While derived from raw materials of natural origin, extensive physical and chemical processes are involved to convert the raw material to the finished product and it is not expected that any pesticide residues will remain intact.

EU Substances of Very High Concern (SVHC)

According to Article 33(1) of Regulation (EC) No. 1907/2006 (REACH), EMPIGEN® CBET does not contain any SVHC substances (Substances of Very High Concern) listed on the latest candidate list in concentrations exceeding 0.1%.

Regulatory Inventory Status

Refer to Section 15 of the Safety Data Sheet.
For details of EU or UK REACH compliance, and other 'REACH-like' schemes (Korea, Turkey, Taiwan), particularly where import is not made directly by Innospec, please contact us at reach@innospecinc.com.

Animal Testing Status

Refer to separate CFI animal testing statement.

Toxicology

For Human Health information, refer to Section 11 of the SDS. No additional data is available other than the SDS.
For Environmental information, refer to Section 12 of the SDS. No additional data is available other than the SDS.
For Endocrine Disruptors, refer to Sections 11 and 12 of the EU SDS. No additional data is available other than the SDS.

Heavy Metals / Elemental Impurities

Results of typical lots of EMPIGEN® CBET and/or similar material are shown below.

NF = Not found, Limit of Detection in parentheses.

TR = Traces detected, actual measured value in parentheses

Test Method: Element-Screening (ICP-MS)

<u>Analyte</u>	<u>Result</u>
Antimony	NF (1 mg/kg)
Antimony	NF (1 mg/kg)
Arsenic	NF (1 mg/kg)
Arsenic	NF (1 mg/kg)
Cadmium	NF (0.1 mg/kg)
Cadmium	NF (0.1 mg/kg)
Chromium	NF (1 mg/kg)
Chromium	NF (1 mg/kg)
Cobalt	NF (1 mg/kg)
Cobalt	NF (1 mg/kg)
Lead	NF (1 mg/kg)
Lead	NF (1 mg/kg)
Mercury	NF (0.1 mg/kg)
Mercury	NF (0.1 mg/kg)
Nickel	NF (1 mg/kg)
Nickel	NF (1 mg/kg)

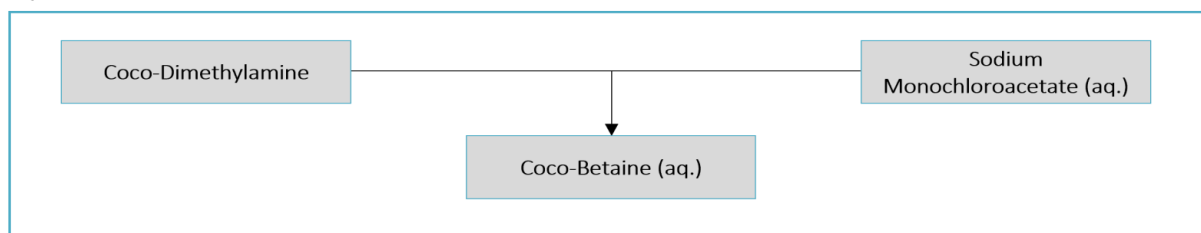
Specific Chemicals of Concern

EMPIGEN® CBET does not contain any of the following intentionally added substances of concern based on product knowledge of our raw materials and manufacturing processes:

- Alfatoxins
- Azo Pigments
- Brominated or fluorinated compounds
- Chlorinated aliphatic compounds
- Ozone Depleting substances
- PCB/PCT
- Talc

Manufacturing Flow Chart

Quaternization



Glossary/Acronyms/Symbols

BBP	Benzyl butyl phthalate
BHT/BHA	Butylated Hydroxytoluene / Butylated Hydroxyanisole
BSE/TSE	Bovine Spongiform Encephalopathy / Transmissible Spongiform Encephalopathy
ca.	Circa
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CLP	Classification, Labelling, and Packaging
DEHP	Diethylhexyl phthalate
DIBP	Diisobutyl phthalate
DIDP	Diisodecyl Phthalate
DINP	Diisononyl Phthalate
DNOP	Di-n-octylphthalate
DTPA	Diethylenetriaminepentaacetic Acid (or Pentetic acid)
EDTA	Ethylene Diamine Tetraacetic Acid
EFFCI	European Federation for Cosmetic Ingredients
GC/MS	Gas Chromatography-Mass Spectroscopy
GMP	Good Manufacturing Practices
ICCR	International Cooperation on Cosmetics Regulation
ICP-MS	Inductively Coupled Plasma Mass Spectroscopy
INCI	International Nomenclature for Cosmetic Ingredients
ISO	International Organization of Standardization
LC/MS	Liquid Chromatography-Mass Spectroscopy
NF	Not found, Limit of Detection in parentheses
NTA	Nitrilotriacetic Acid
PCB	Polychlorinated Biphenyls
PCT	Polycyclohexylenedimethylene Terephthalate
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
TR	Traces detected, actual amount detected in parentheses
†	Less frequent testing, result not intended as a specification

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Innospec provides this information based on its knowledge of its manufacturing processes, raw materials and of the products and the impurities that are known or likely to be created from these processes or present in raw materials. We examine the specification of the raw materials we buy, but we may not have confirmed the presence and therefore cannot guarantee the absence of trace substances within raw materials which are not declared in the specification or Safety Data Sheet (SDS). The facts stated and the recommendations made are based on our own research and/or the research of others. No guarantee of their accuracy is made and unless otherwise expressly provided by law or in written contract, the materials are sold without warranties, expressed or implied, in particular without guarantee as to suitability for particular purpose. Innospec assumes no responsibility for injury or damage to users or third parties. Recipient agrees to assume all risk and liability whether used singly or in combination with other materials.

For non EU based customers, use of this and other documents in isolation is insufficient to confirm REACH compliance of the Innospec product concerned. In order to comply with EU REACH regulations (Title II, Chapter 1, Article 8) and to secure documentation to allow this product to be imported into the EU please contact Innospec to join our "Only Representative" and Declaration of Conformity Program."