



LESSIVE POTASSE 50% CPP COSMET

Date de mise à jour : 01/10/2022

Version FT : 4

USAGES COMPATIBLES : Auxiliaire technologique pour denrées alimentaires, Cosmétique

SPÉCIFICATIONS DE VENTE

Paramètres	Unité	Mini - Maxi	Méthode/Commentaires
Aspect	Liquide, limpide, incolore		
Titre	%	49,0 - 51,0	Titrateur

SPÉCIFICATIONS DE VENTE GARANTIES PAR LES PRODUCTEURS

Paramètres	Unité	Mini - Maxi	Méthode/Commentaires
Arsenic (As)	mg/kg	≤ 3	
Mercuré (Hg)	mg/kg	≤ 1	
Plomb (Pb)	mg/kg	≤ 2	
Carbonates potassium	% m/m	≤ 3,5	K2CO3
Matières insolubles dans l'eau	une solution à 5% est totalement limpide et incolore		

INFORMATIONS PRODUIT

Synonymes	potasse caustique
DDM (date durabilité minimum)	24 mois

Ce produit n'a pas à être déclaré en tant que substance à l'état nano-particulaire tel que défini à l'article R523-12 du décret 2012-232.

ORIGINE PRODUIT

Process mis en oeuvre	électrolyse procédé membrane
Matières premières	minérale
Producteur	multi -producteurs
Site de production	Europe

AUXILIAIRE TECHNOLOGIQUE POUR L'ALIMENTATION HUMAINE - USAGE RÉGLEMENTÉ

Ce produit répond aux critères de pureté des auxiliaires technologiques pour l'alimentation humaine tels que définis dans le décret 2011-509, l'arrêté du 19-10-2006 et actes modificatifs.

Ce produit est un auxiliaire technologique listé à l'annexe IA de l'arrêté du 19-10-2006 et actes modificatifs.

Ce produit a fait l'objet de déclarations auprès de la DGCCRF selon article 8 du décret 2011-509 pour un ou des usages en tant qu'auxiliaire technologique pour denrées alimentaires. Il revient à l'utilisateur de s'assurer que les conditions d'autorisation et d'utilisation qui y sont définies, sont respectées et compatibles avec l'emploi prévu par celui-ci. La liste des usages déclarés est disponible sur le site Web de la DGCCRF : https://www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/produits_alimentaires/liste-auxiliairestechnologiques-declares-v1.pdf

CATÉGORIE AUXILIAIRE TECHNOLOGIQUE	DENRÉES ALIMENTAIRE AUTORISÉE	CONDITIONS D'EMPLOI - FONCTION -	DOSE RÉSIDUELLE MAXIMALE	DATE DE FIN D'AUTORISATION
Agent de neutralisation	caséinates et caséines alimentaires	à la dose strictement nécessaire pour obtenir l'effet recherché	dose techniquement inévitable	illimité

GARANTIES POUR L'ALIMENTATION HUMAINE

PRODUIT GRADE CPP :

Ce produit répond aux critères de pureté des additifs alimentaire définis par le règlement 231/2012/UE, mais n'est pas fabriqué selon un plan de maîtrise sanitaire complet.

Ne pas utiliser en tant qu'additif dans l'alimentation humaine ou animale.

Ce produit est listé comme constituant autorisé dans les produits de nettoyage des matériaux et objets destinés à être mis au contact des denrées alimentaires selon l'arrêté du 08/09/1999 et actes modificatifs en vigueur.



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GARANTIES POUR LA COSMÉTIQUE

Ce produit convient à un usage en tant qu'ingrédient pour la fabrication de produits cosmétiques selon le règlement 1223-2009-CE et ses actes modificatifs.

Dénomination INCI	POTASSIUM HYDROXIDE
Fonctions cosmétiques selon commission 2006-257-CE	agent tampon
Substances interdites	Ce produit ne contient aucune des substances interdites listées dans l'annexe II du règlement 1223-2009-CE et actes modificatifs relatifs aux produits cosmétiques.
Substances faisant l'objet de restrictions	Ce produit est une substance faisant l'objet de restrictions pour les produits cosmétiques. Se référer à l'annexe III du règlement 1223-2009 et actes modificatifs avant toute utilisation. type de restriction : III/15a, 15d
Nanomatériaux au sens de la réglementation cosmétique (R1223-2009-CE)	Ce produit ne contient pas de "nanomatériaux", cad aucun matériau insoluble ou bio-persistant fabriqué intentionnellement et de structure de 1 à 100 nm.
Substances parfumantes allergènes étiquetables	Ce produit ne contient aucune des 26 substances parfumantes allergènes étiquetables tel que définit dans la directive 2003-15-CE.
Expérimentation animale	Aucun test sur les animaux n'a été réalisé depuis la mise en application de la réglementation cosmétique le 11 mars 2009.
Conservateur (type et concentration)	Aucun conservateur n'est ajouté au produit.
Antioxydant (type et concentration)	Aucun antioxydant n'est ajouté au produit.
Séquestrant/complexant (type et concentration)	Aucun séquestrant/complexant n'est ajouté au produit.
Colorant (type et concentration)	Aucun colorant n'est ajouté au produit.
Filtre UV (type et concentration)	Aucun filtre ultra violet n'est ajouté au produit.
Statut CMR	Ce produit n'est pas une substance classée cancérigène, mutagène ou toxique pour la reproduction (CMR). Pour plus d'informations, se référer à la section 11 de la fiche de données de sécurité.
Statut SVHC	Ce produit n'est pas une substance extrêmement préoccupante (SVHC). Pour plus d'informations, se référer à la section 15 de la fiche de données de sécurité.

AUTRES GARANTIES PRODUIT

Statut OGM	Sur la base des informations dont nous disposons sur les matières premières et le process mis en oeuvre, aucun OGM n'est attendu dans ce produit.
Statut pesticides	Sur la base des informations dont nous disposons sur les matières premières et le process mis en oeuvre, aucun pesticide n'est attendu dans ce produit.
Statut ESB/EST	Sur la base des informations dont nous disposons sur les matières premières et le process, ce produit est exempt de risque de contamination par ESB/EST.
Statut ionisation	Sur la base des informations dont nous disposons sur le process, aucun traitement par ionisation n'est effectué par le producteur (attestation producteur sur demande).

INFORMATIONS COMPLÉMENTAIRES

Conditions de stockage :

Conserver dans un endroit sec, frais et bien ventilé. Conserver dans des conteneurs hermétiquement clos. Conserver à l'abri de la lumière solaire directe. Conserver à l'abri de l'humidité. Conserver à l'écart des: Acides

Les fiches de données de sécurité sont envoyées par mail selon les dispositions réglementaires lors de l'expédition de nos produits. Elles sont également disponibles auprès de notre force de vente.



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Les déclarations de ce document proviennent de sources que nous considérons être dignes de foi. Elles ne dédouanent pas l'utilisateur de procéder à ses propres contrôles et sont rédigées sur la base de nos connaissances à la date de rédaction. Il appartient à l'acheteur et à l'utilisateur final le cas échéant, de s'assurer seuls et en dernier lieu de l'adéquation du produit au regard de l'usage prévu par leur secteur d'activité et des dispositions législatives et réglementaires en vigueur. Litiges : Le tribunal de commerce de Rennes est seul compétent.

Fin du document



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Regulatory Information

Potassium Hydroxide Solutions

CAS Name :	Potassium Hydroxide
CAS-Number:	1310-58-3
Publishing date:	09/03/2023
Prepared by:	Quality Department
Company:	VYNOVA PPC SAS – 95, rue du général de Gaulle -68802 THANN- France
Document validity:	This document replaces all documents published prior to the above mentioned publishing date and is valid for a period of 1 calendar year.

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1 PRODUCT DEFINITION

Potassium hydroxide solutions of Vynova PPC SAS, hereafter referred to as the PRODUCT, consists of various concentrations of aqueous potassium hydroxide solutions, ranging from 45 to 50% potassium hydroxide.

- **Standard Specifications KOH 50%** : (QSE DO 1213/ SP/KOH 50%/Membrane)
- **Standard Specifications KOH 48%** : (QSE DO 2195/ SP/KOH 48%/Membrane)
- **Standard Specifications KOH 47%** : (QSE DO 2146/ SP/KOH 47%/Membrane)
- **Standard Specifications KOH 46%** : (QSE DO 2123/ SP/KOH 46%/Membrane)
- **Standard Specifications KOH 45%** : (QSE DO 2122/ SP/KOH 45%/Membrane)

For more information on the product specification, contact your Area Sales Manager or Representative

2 PRODUCT ORIGIN

2.1 Production Process

The PRODUCT is synthetically manufactured by membrane electrolysis of a potassium chloride solution, diluted with water as per PRODUCT specification.

2.2 Product Traceability

The PRODUCT is manufactured in a continuous process, not batch. Finished product storage tanks are sampled and analyzed on a daily basis. PRODUCT is released upon confirmation that its analysis results are within specification. Vynova PPC SAS tracks the lot number(s) of the PRODUCT shipped to the CUSTOMER.

Detail of the establishment of the Lot Number : XXXX AA NNN C with :

XXXX : SAP Number code / AA: Year (22 for 2022) / NNN: order number from 001 to 999 / C: 4,5,6,7,9 : KOH 50%

2.3 Mercury Statement

The production process is mercury free, which results in mercury levels in the PRODUCT typically < 0.001 mg/kg (detection limit)

2.4 Declaration of Non-Animal, Non-Human, Non-Cell-Culture or Non-Enzyme Origin Statement

The PRODUCT is chemically synthesized and does not contain any animal, human, cell culture or enzyme derived products. The PRODUCT is not derived from animal, human, cell culture or enzyme derived products.

2.5 Conflict Mineral Sources Statement

To the best of our today's knowledge we can state that none of our products is intentionally manufactured with or using any conflict minerals in the aforementioned meaning.

2.6 Palm Oil Statement

No raw materials based on palm oil or palm kernel oil derivatives are used in during the production of the PRODUCT. The PRODUCT is produced in dedicated manufacturing plant.

3 REACH

3.1 EU – REACH and CLP

We certify that the PRODUCT is in compliance with REACH Regulation (EC) No. 1907/2006 as amended by regulation (EU) N°2020/878.

The substance in this PRODUCT is registered. The REACH registration number and the identified safe uses are communicated in the Safety Data Sheet (SDS).

The PRODUCT is classified as hazardous, meaning that an exposure assessment is required. Please refer to the Safety Data Sheet.

3.2 EU - REACH Registration

The substance in the PRODUCT is produced or imported at a volume of > 1000 ton/year.

A full registration was submitted in 2010, under the registration number 01-2119487136-33-0006.

3.3 Substance of Very High Concern Statement – Candidate List

We hereby certify that the PRODUCT does not contain any Substance of Very High Concern (SVHC) in amounts > 0.1% (w/w) listed on the most current Candidate list according to Art. 59 ([Candidate List of substances of very high concern for Authorisation - ECHA \(europa.eu\)](#) – Last update : 17 January 2023)

3.4 REACH Annex XIV Statement - Authorization List

We hereby certify that the PRODUCT does not contain any substances in amounts > 0.1% (w/w) listed on the most current Authorization List (Annex XIV) published on the ECHA website [Authorisation List - ECHA \(europa.eu\)](#)

3.5 REACH Annex XVII Statement - Restricted Substance List

We hereby certify that the PRODUCT does not contain any substances in amounts > 0.1% (w/w) listed on the most current list of substances restricted under REACH (Annex XVII) published on the ECHA website ([Substances restricted under REACH - ECHA \(europa.eu\)](#) – Last update : 4 July 2022)

3.6 Carcinogen, Mutagen, Reprotoxic Substance Statement

The PRODUCT does not contain any Carcinogen, Mutagen, Reprotoxic (CMR) substances above classification limits specified in Regulation (EU) No. 1272/2008 on classification, labelling and packaging of substances and mixtures.

4 FOOD & FEED (CONTACT) CONFORMITY

4.1 HACCP statement

Vynova PPC SAS has established a food quality and safety assurance system, analyzing the risks according to the HACCP methodology, for the PRODUCT.

However, Vynova PPC SAS would like to point out that it is the sole responsibility of the manufacturer of materials or articles intended for human and animal consumption (contact), containing this PRODUCT as a component, to ensure that these materials or articles finished meet all relevant regulatory requirements and that they do not endanger human/animal health, nor cause an unacceptable change in the composition of the foodstuff or a deterioration in its organoleptic characteristics.

4.2 Europe

4.2.1 European Community / Declaration of Compliance (DoC)

The PRODUCT complies with the regulation (EC) No. 1935/2004 and regulation (EC) 10/2011 as follows:

FCM Substance No.	399
Ref. No.	81600
CAS - No.	1310-58-3
Substance name	Potassium hydroxide
Use as additive or polymer production aid	yes
Use as monomer or other starting substance	no
FRF applicable	no
SML	not applicable
SML(T)	not applicable
Restrictions and specifications	not applicable
Notes for the verification of compliance	no restrictions or SML

The PRODUCT meets the purity criteria specified in regulation (EC) No. 231/2012, laying down specifications for food additives listed in Annex II and III of regulation (EC) No. 1333/2008:

E525 – Potassium Hydroxide

Component	Purity requirement
Water insoluble matter	A 5 % solution is completely clear and colorless
Carbonate	Not more than 3,5 % (as K ₂ CO ₃)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

Additional Information: Finished food contact materials or articles containing this PRODUCT as a component, need to comply inter alia with Overall Migration Limit (OML) requirements - as specified in EU - Regulation 10/2011. Verification of compliance with migration limits (OML and SML) should be carried out in accordance with the rules laid down there. We would like to point out that it is the sole responsibility of the manufacturer of the final material or article to assure compliance with the OML and SML requirements under actual and foreseeable conditions of use, and to check it on a regular basis. The manufacturer of food contact materials or articles, containing this PRODUCT as a component, must in particular ascertain that these finished materials or articles meet the general regulatory requirement that they do not endanger human health, or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof.

4.2.2 Maximum Impurity Levels for Foodstuffs

Regulation (EC) 1881/2006 and its amendments sets the maximum levels for certain contaminants in foodstuffs. Our PRODUCT is not foodstuff as such, however may be used for the production of it. It is the responsibility of the foodstuff manufacturer to ensure content levels of these contaminants, listed in the Annex of Regulation (EC) 1881/2006, do not exceed the permitted maximum content for their intended foodstuff application.

1. Nitrate: *not present*
2. Mycotoxins: *not present*
3. Metals:
 - ✓ **Mercury** : present, see Product Specification for their respective maximum concentration levels
 - ✓ Tin (inorganic) : not present
4. 3-monochloropropane-1,2-diol: *not present*
5. Dioxins (PCDDs), Furans (PCDFs) and polychlorinated biphenyls (PCBs): *not present*
6. Polycyclic aromatic hydrocarbons (PAH): *not present*
7. Melamine and its structural analogues: *not present*
8. Inherent plant toxins: *not present*

Possible contaminants listed as “not present” are analyzed not to be present in our PRODUCT and therefore are not analyzed on a regular basis. Changes in raw materials, process aids, production process, installation changes may trigger a need for us to re-evaluate impurity presence and concentrations.

4.2.3 Maximum Levels for Undesirable Substances in Animal Feed

Directive 2002/32/EC lists the maximum permitted content of undesirable substances in animal feed. Our PRODUCT is not animal feed as such, however may be used for the production of it. It is the responsibility of the animal feed manufacturer to ensure content levels of these undesirable substances, listed in Annex I of Directive 2002/32/EC, do not exceed the permitted maximum content for their intended feed application.

1. **Arsenic:** *present, see Product Specification for their respective maximum concentration level*
2. **Lead:** *present, see Product Specification for their respective maximum concentration level*
3. Fluorine: *not present*
4. **Mercury:** *present, see Product Specification for their respective maximum concentration level*
5. Nitrites: *not present*
6. **Cadmium:** *present, see Product Specification for their respective maximum concentration level*
7. Aflatoxin B1: *not present*
8. Hydrocyanic acid: *not present*
9. Free gossypol: *not present*
10. Theobromine: *not present*
11. Volatile mustard oil: *not present*
12. Vinal thioxazolidone: *not present*
13. Rye ergot: *not present*
14. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination: *not present*
15. Castor oil plant – *Ricinus communis L.: not present*
16. *Crotalaria spp.: not present*
17. Aldrin: *not present*
18. Dieldrin: *not present*
19. Camphechlor: *not present*
20. Chlordane: *not present*
21. DDT: *not present*
22. Endosulfan: *not present*
23. Endrin: *not present*
24. Heptachlor: *not present*
25. Hexachlorobenzene (HCB): *not present*
26. Hexachlorocyclohexane (HCH): *not present*
27. Dioxins (PCDDs), Furans (PCDFs) and Polychlorinated Biphenyls (PCBs): *not present*
28. Apricots: *not present*
29. Bitter almond: *not present*
30. Unhusked beech mast: *not present*
31. Camelina: *not present*
32. Mowrah, Bassia, Madhuca: *not present*
33. Purguera: *not present*
34. Croton: *not present*
35. Indian mustard: *not present*
36. Sareptian mustard: *not present*
37. Chinese mustard: *not present*
38. Black mustard: *not present*
39. Ethiopian mustard: *not present*

Possible contaminants listed as “*not present*” are analyzed not to be present in our PRODUCT and therefore are not analyzed on a regular basis, with an exception of (27) dioxins, furans and polychlorinated biphenyls. Changes in raw materials, process aids, production process, installation changes may trigger a need for us to re-evaluate impurity presence and concentrations.

4.2.4 Germany Food / Food Contact Statement

The PRODUCT fulfils the requirements of the German recommendations of the BfR (Federal Institute for risk assessment) on contact with food, limits on concentration in final product may [apply](#):

- XIV. Polymer Dispersions
- XV. Silicones
- XXI. Commodities based on Natural and Synthetic Rubber
- XLVIII. Materials for Coating the Outside of Hollow Glassware

4.2.5 Genetically Modified Organisms (GMO) Statement

Vynova PPC SAS confirms that the PRODUCT is not manufactured using intentionally any products of animal, vegetable or GMO origin.

We further confirm that in the PRODUCT no GMO substances are present in amounts of:

- > 0.9% according to Regulation (EG) No. 1829/2003 and 1830/2003.
- > 0.1% according to national German EG - Gentechnik - Durchführungsgesetz (EGGenTDurchfG)

4.2.6 Chlorate and perchlorate statement

The PRODUCT, produced by Vynova PPC SAS, does not contain:

- chlorate in concentrations above 20 mg/kg
- perchlorate in concentrations above 1 mg/kg (detection limit)

4.2.7 Substances or Products causing Allergies, Intolerances or Cross - allergies

Vynova PPC SAS confirms that the PRODUCT does not contain any allergens or other substances causing intolerances according to Annex II of Regulation (EU) No. 1169/2011 and amendments.

4.2.8 Water Statement

Water used for production of the PRODUCT is taken from various sources: surface water, ground water, municipal water. Where needed, water that comes into direct contact with the PRODUCT is treated to ensure it meets the purity requirements in accordance with EU Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

4.2.9 Swiss Food Contact Statement

The PRODUCT fulfils the requirements of the Swiss ordinance of the FDHA on materials and articles intended to come into contact with food (Commodities Regulation), SR 817.023.21, Annex 6 (List of admissible substances for the production of glass foils and requirements for these substances), in effect as of May 1, 2017.

4.2 United States

4.2.1 US FDA Food Facility Registration

Vynova PPC SAS's production site, located in Thann (FRANCE) is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act

- U.S. FDA Registration No.: 10861187962
- U.S. Agent for FDA Communications: Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177
Fax: +1-757-224-0179.
Email: info@registrarcorp.com info@registrarcorp.com

4.2.2 US Food Statement – GRAS

The PRODUCT fulfils the requirements of [eCFR :: 21 CFR 184.1631 -- Hydroxyde de potassium](#), on direct food substances affirmed as Generally Recognized As Safe (GRAS) – potassium hydroxide

4.2.3 USDA National Organic Program Statement

With regards to [§205.105](#) ("Allowed and prohibited substances, methods, and ingredients in organic production and handling"), VYNOVA PPC SAS PRODUCT:

1. Is listed on the [National List of Allowed and Prohibited Substances](#)
 - ✓ §205.601 Synthetic substances allowed for use in organic crop production: (j) As plant or soil amendments - (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of **potassium hydroxide** or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
 - ✓ §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))": **Potassium hydroxide**—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.
2. is manufactured synthetically and not grown with the use of sewage sludge.
3. is manufactured synthetically and is not derived from a genetically modified organism (GMO).
4. does not contain any residual synthetic solvents.
5. is not processed with ionizing radiation – see Statement 6.14 in this document

4.3 General

4.3.1 Food Chemicals Codex Statement

The PRODUCT meets the specifications and maximum impurities indicated in the Food Chemicals Codex 13th Ed.

Component	Purity requirement
Total alkali	Not less than 97,0% and no more than 103,0% (as KOH)
Carbonate	Not more than 3,5 % (as K ₂ CO ₃)
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

4.3.2 TSE/BSE Statement

Vynova PPC SAS confirms that the PRODUCT is produced solely synthetically, and no material used in the manufacture is of bovine or animal origin.

We further confirm that no materials of animal origin are present at any time during production or are used for production in the same plant.

Therefore, with regards to the conditions of our production process and the raw materials used, the BSE/TSE risk is, according to our knowledge, is not considered as relevant.

4.3.3 Kosher Certification

The PRODUCT is synthetically manufactured by membrane electrolysis of a potassium chloride solution from which water is evaporated to obtain potassium hydroxide flakes. It is not derived from nor does it contain any animal products, including those derived from wheat, barley, spelt, rye or oats that are excluded from Kosher for Passover. None of the raw materials used in its manufacture are derived from animal products. Our manufacturing plants are dedicated to the manufacture of the PRODUCT and no animal materials are used when cleaning operations are conducted. During the evaporation process, very small quantity of plant-based process aid is added.

This process aid is Kosher certified by the BETH DIN du grand rabbinat de Strasbourg – Rabbi SZMERLA – Strasbourg (France)

4.3.4 Halal Certification

The PRODUCT is not derived from, nor does it contain, any product of animal origin or ethyl alcohol. The manufacturing plants are dedicated to the manufacture of the PRODUCT and no animal materials or ethyl alcohol are used when cleaning operations are conducted.

A certification established by the Lyon mosque is in progress.

4.3.5 Gluten, Aflatoxins, Mycotoxins, Melamine and Latex Statement

The PRODUCT and associated packaging are free of gluten, aflatoxins, mycotoxins, melamine and latex.

4.3.6 Bacteria and microorganisms

The high pH property of the PRODUCT does not make it a viable environment for bacteria and microorganisms.

5 CONSUMER GOODS & PHARMACEUTICALS STATEMENTS

5.1 Cosmetics / Allergens Statement

The PRODUCT is listed on the EU Cosmetic Ingredients Inventory – see [CosIng - Cosmétiques - CROISSANCE - Commission européenne \(europa.eu\)](#)

INCI Name	POTASSIUM HYDROXIDE
Description	Potassium Hydroxide is the inorganic base KOH
INN Name	potassium hydroxide
Ph. Eur. Name	kalii hydroxidum
CAS #	1310-58-3
EC #	215-181-3
Chemical/IUPAC Name	Potassium hydroxide
Cosmetic Restriction	Annex III/15a & 15d
Other Restriction(s)	
Functions	BUFFERING
SCCS opinions	1527/14 - Opinion on Potassium hydroxide (KOH) as callosity softener/remover
Identified INGREDIENTS or substances e.g.	

We hereby confirm that the PRODUCT is neither listed on Annex II of Regulation (EC) No. 1223/2009.

5.2 Micro-plastics Statement

Vynova PPC SAS confirms that the PRODUCT is free from micro-plastics.

They are not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

5.3 Residual Solvents Statement

None of the solvents listed in the §5.4 Residual Solvents (EP9.5) and <467> Residual Solvents (USP 42) are used or produced during the manufacture of the PRODUCT.

5.4 Animal testing

The PRODUCT manufactured by VYNOVA PPC SAS has never been tested on animals on our behalf.

5.5 Elemental Impurities Statement

All elemental impurities in the PRODUCT are compliant with the Class 1, Class 2A/2B and Class 3 permitted oral concentrations for the individual component option (USP) and option 1 (ICH).

Element	Class	Oral Concentration(in µg/g)	Parenteral Concentration (in µg/g)	Inhalation Concentration (in µg/g)
Cd	1	0.5	0.2	0.2
Pb	1	0.5	0.5	0.5
As	1	1.5	1.5	0.2
Hg	1	3	0.3	0.1
Co	2A	5	0.5	0.3
V	2A	10	1	0.1
Ni	2A	20	2	0.5
Tl	2B	0.8	0.8	0.8
Au	2B	10	10	0.1
Pd	2B	10	1	0.1
Ir	2B	10	1	0.1
Os	2B	10	1	0.1
Rh	2B	10	1	0.1
Ru	2B	10	1	0.1
Se	2B	15	8	13
Ag	2B	15	1	0.7
Pt	2B	10	1	0.1
Li	3	55	25	2.5
Sb	3	120	9	2
Ba	3	140	70	30
Mo	3	300	150	1
Cu	3	300	30	3
Sn	3	600	60	6
Cr	3	1100	110	0.3

5.6 Pharmacopeia Statement

The PRODUCT meets the specifications and maximum impurities indicated in the Pharmacy Monographs:

German DAB 1999 - Kap. 4 – Reagent

USA - USP – NF40

EU – EP 10

Component	Purity requirement
Carbonate	Maximum 2,0% (as K ₂ CO ₃)
Chlorides	Maximum 200 ppm
Phosphates	Maximum 100 ppm
Sulfates	Maximum 200 ppm
Iron	Maximum 10 ppm
Sodium	Maximum 1,0%

6 ADDITIONAL REGULATIONS / STATEMENTS

6.1 RoHS & WEEE Statement

The RoHS and WEEE Directives restrict the maximum concentrations of certain hazardous substances in electrical and electronic equipment, as listed below (directives EU/2011/65 and amendment EU/2015/863):

- Lead 0.1%
- Mercury 0.1%
- Cadmium 0.01%
- Hexavalent Chromium 0.1%
- Dibutyl phthalate 0.1%
- Polybrominated Biphenyls 0.1%
- Polybrominated Diphenyl Ethers 0.1%
- Bis(2-ethylhexyl)phthalate 0.1%
- Butyl benzyl phthalate 0.1%
- Diisobutyl phthalate 0.1%

Polybrominated biphenyls, polybrominated diphenyl ethers and phthalates are not used in the production the PRODUCT nor are they produced as impurities during the manufacturing processes. All metal residues in the PRODUCT are below the indicated limit values.

6.2 Biocide Statement

The PRODUCT does not contain any biocidal active substances.

6.3 Pesticides and Herbicides Statement

The product adheres to Regulation (EU) No. 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

The PRODUCT and starting raw materials as well as associated packaging, do not contain any pesticides and herbicides.

Remark: Chlorine is produced

6.4 Benzene Statement

Vynova PPC SAS confirms that the PRODUCT is free from Benzene.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.5 Phthalate Statement

To the best of our knowledge the PRODUCT, the raw materials or all other materials used in the manufacturing process do not contain the following substances:

- Diisobutyl phthalate (DIBP) CAS - No. 84-69-5
- Dibutyl phthalate (DBP) CAS - No. 84-74-2
- Bis(2-ethylhexyl)phthalate(DEHP) CAS - No. 117-81-7
- Dihexyl phthalate (DHP) CAS - No. 84-75-3
- Dicyclohexyl phthalate (DCHP) CAS - No. 84-61-7

These substances are not added during the synthesis steps. A formation of the above - mentioned substances during synthesis is unlikely. However, we want to point out that the products are not tested with respect to the mentioned substances.

6.6 Bisphenol- A-diglycidylether Statement

We confirm that the PRODUCT is free from BADGE (Bisphenol-A-diglycidylether, CAS: 1675-54-3).

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.7 Alkylphenols and Alkylphenoethoxylate Statement

We confirm that the PRODUCT is free from alkylphenols (APs) or alkylphenoethoxylates (APEOs) – including all isomers.

They are not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.8 MOSH, MOAH and PAH Statement

Vynova PPC SAS confirms that the PRODUCT is free from Mineral Oil Saturated Hydrocarbons (MOSH), Mineral Oil Aromatic Hydrocarbons (MOAH) and Polycyclic Aromatic Hydrocarbons (PAH) due to the absence of a carbon source in the raw materials and processing aids. Therefore, no analysis is performed on a regular basis.

6.9 Fluorinated compounds Statement

Herewith we confirm that the PRODUCT is free from:

- Pentadecafluorooctanoic acid (PFOA)
- Perfluorooctane sulfonate (PFOS)
- Fluorotelomeric alcohol FTOH 8-2
- Fluorotelomeric alcohol FTOH 10-2
- Other fluorinated compounds

These substances are not intentionally added or produced during the manufacturing process of the PRODUCT and therefore are not analyzed on a regular basis

6.10 Asbestos Statement

The PRODUCT and starting raw materials as well as associated packaging, do not contain any asbestos.

6.11 Dioxins / Furans / Polychlorinated Biphenyls (PCB) Statement

The PRODUCT and starting raw materials as well as associated packaging, do not contain any dioxins, furans (PCDDs/Fs) or polychlorinated biphenyls (PCBs).

6.12 Nano Statement

The PRODUCT does not contain any nano-materials as defined by Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU). Registrations according to national laws are not required.

6.13 California Prop 65

The PRODUCT is not listed on California Proposition 65 dd. February 25, 2022 except the following substances, which are not intentionally added but can be present as impurities:

Component	Purity requirement / Typical value (TV)
Nickel	TV/ <1 mg/kg
Arsenic	TV/ <0.1 mg/kg
Cadmium	TV/ <0.1 mg/kg
Chromium	TV/ <1 mg/kg
Cobalt	TV/ <1 mg/kg
Lead	TV/ <0.5 mg/kg
Mercury	TV/ <0.05 mg/kg

6.14 Ionising Radiation / Irradiation / EO / Natural Radiation Statement

The product is not treated by ionizing radiation according to Directive 1999/2/EC and amendments concerning food and food ingredients.

The PRODUCT is not sterilized by radiation or treated with Ethylene Oxide (EO) at any point of our manufacturing process.

We declare that there is no external contamination of radioactivity in the PRODUCT supplied by VYNOVA PPC SAS. However the element K in KOH contains 99.988% K-39 and K-41 isotopes which are not radioactive and 0.012% K-40 which is a radioactive isotope with a very long half-life of 1.251×10^9 years. K-40 is the largest source of natural radioactivity in animals, including humans

6.15 Genotoxic Impurities Statement

We confirm that the PRODUCT does not contain any genotoxic impurities.

6.16 US DEA Statement

We confirm that the PRODUCT does not contain any substances listed on List I or List II of [eCFR :: 21 CFR 1310.02 -- Substances couvertes.](#)

6.17 Volatile Organic Compounds Statement

We confirm that the PRODUCT does not contain any Volatile Organic Compounds (VOC).

6.18 Aldehyde Statement

We confirm that the PRODUCT does not contain any aldehydes.

6.19 Paraben Statement

We confirm that the PRODUCT is free from paraben.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.20 Dichlorobenzene Statement

Vynova PPC SAS confirms that the PRODUCT is free from dichlorobenzene.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.21 Nitrosamines Statement

Vynova PPC SAS confirms that the PRODUCT is free from nitrosamines.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.22 Quaternary Ammonium Compounds Statement

Vynova PPC SAS confirms that the PRODUCT is free from quaternary ammonium compounds (QAC)..

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.23 Preservatives, Colorants and Fragrances Statement

Vynova PPC SAS confirms that the PRODUCT does not contain preservatives, colorants or fragrances.

7 INTERNATIONAL INVENTORY INFORMATION

Inventory status of the components of the PRODUCT

Inventory	Country / Region	Status ¹
AICS	Australia	In compliance
DSL / NDSL	Canada	In compliance
ECSI	Taiwan	In compliance
EINECS	European Union	In compliance
IECSC	China	In compliance
KECI	Korea	In compliance
ENCS	Japan	In compliance
NZIoC	New Zealand	In compliance
PICCS	Philippines	In compliance
TSCA	United States of America	In compliance

8 SAFETY DATA SHEETS

Vynova PPC SAS provides safety data sheets to its customers to inform about the PRODUCT's properties and potential hazardous effects on humans and the environment.

Contact an account representative if you need a safety data sheet

DISCLAIMER

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¹ In compliance means: all components of the PRODUCT are listed on the above mentioned inventories or are exempted from listing and are not being offered in violation of any rule or order under the respective laws.