

EuroVanillin Pure

REGULATORY QUALITY BROCHURE



Borregaard

*This document states and certifies
the regulatory and quality aspects
for the products in the Borregaard
EuroVanillin Pure range.*

Learn more about our Vanillin range on www.borregaard.com

Borregaard AS

Name: Borregaard AS, Business Unit: BioVanillin
Head Office Address: Hjalmar Wessels vei 6, 1721 Sarpsborg, Norway
Homepage: www.vanillin.com
VAT ID number: 895623032

Emergency Contact: Borregaard 24-hour Security Office
Tel: +476911800

Table of contents

The Pure range products	4
Regulatory compliance and food grade status	4
Certification	4
Labelling	5
Declarations	6
Nutritional content	6
Allergens	6
Microbiological content.....	7
Mineral and heavy metal content.....	8
Solubility.....	9
FSMA compliance.....	9
Food fraud.....	10
Food defence	11
Foreign object control.....	11
REACH (Regulation (EC) 1907/2006).....	12
Residual solvents.....	13
Polycyclic Aromatic Hydrocarbons (PAHs).....	13
Pesticide, mycotoxin (aflatoxin etc.), and dioxin	13
TSE/BSE	13
Proposition 65 status	14
GMO.....	14
Ionising radiation	15
Nano particles	15
Phthalates and plasticisers.....	15
Nitrosamines.....	15
Palm oil.....	16
Alcohol	16
Vegetarian and vegan	16
WADA.....	16
Non-animal origin	16
Animal testing	16
Manufacturing processes:.....	17

Packaging 18
Packaging food contact..... 18
Traceability 19
Hygiene and cleaning management 20

The Pure range products

The EuroVanillin Pure range consists of:



The products supplied by Borregaard comply with relevant regulations for food additives, e.g., EU Flavour and Hygiene Regulation (Regulations (EC) No. 1334/2008 and No. 852/2004). The product is approved for use in food products as flavouring. There are no allergens in the product, e.g., EU Regulation (EC) no. 1169/2011 on food information to consumer. For more information see the individual product specifications and safety data sheets which are all available on our website www.vanillin.com.

Regulatory compliance and food grade status

The products supplied by Borregaard AS are manufactured and distributed in accordance with relevant regulations regarding food additives, e.g., comply with relevant regulations for food additives, e.g., **EU Flavour and Hygiene Regulation (Regulations (EC) No. 1334/2008 and No. 852/2004)** and the **US Code of Federal Regulations; 21 CFR § 172 and 182**. The products are considered to be of food grade and approved for use in food products as flavouring.

Certification

All of Borregaard's EuroVanillin products comply with the Food Safety System Certification; **FSSC 22000**. This is an ISO-based internationally accepted certification scheme for auditing and certification of food safety in the whole supply chain.

The system involves Hazard Analysis and Critical Control Points (**HACCP**), a management system for food safety. The products are controlled for biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

Borregaard is also ISO certified; **ISO 9001**, **ISO 14001**, and **ISO 50001**. ISO 9001 ensures that customers get consistent, good quality products and services.

Borregaard has a platinum rating in EcoVadis, the world's largest and most trusted provider of business sustainability ratings. EcoVadis is dedicated to driving improvements in responsible and ethical business practices in global supply chains. Borregaard's EcoVadis registration number is: **CW732719**

All EuroVanillin products are **kosher**, and **halal** certified.

Labelling

EuroVanillin Supreme and Regular

Europe

When not intended for sale to the final consumer, this product shall be labelled as "flavouring" or a more specific name or description of the flavouring e.g., "vanillin" according to Regulation (EC) No 1334/2008

USA

The product shall be labelled as "vanillin" or "artificial vanillin flavour" when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, according to CFR101.22(g)

EuroVanillin Aromatic

Europe

When not intended for sale to the final consumer, this product shall be labelled as "flavouring" or a more specific name or description of the flavouring e.g., "ethyl vanillin" according to Regulation (EC) No 1334/2008

USA

The product shall be labelled as "ethyl vanillin", "artificial flavour" or "artificial vanillin flavour" when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, according to CFR101.22(g)

Declarations

Nutritional content

Flavourings are exempted from the requirement of the mandatory nutrition declaration given in section 3 of the food information regulation, e.g., annex V of Regulation (EC) no. 1169/2011. Dosages used in traditional food applications are very low and will not contribute to a measurable increase in nutrient content/energy in the customer's end product.

Allergens

In the context of the European Regulation N°1169/2011 and its subsequent amendments, general principles, requirements, and responsibilities governing food information to consumers, and in particular food labelling have been laid down. When used in the production of food and still present therein, certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people and constitute a danger to the health of those concerned.

These substances causing allergies or intolerances, as listed in Annex II to this regulation, are part of the mandatory food information.

Allergens and their derivatives	Present in the product	Present in the manufacturing facilities
Celery	No	No
Cereals containing gluten (such as barley and oats)	No	No
Crustaceans (such as prawns, crabs and lobsters)	No	No
Eggs and egg products	No	No
Fish and fish products	No	No
Lupin	No	No
Milk and milk products (including lactose)	No	No
Molluscs (such as mussels and oysters)	No	No
Mustard	No	No
Peanuts	No	No
Sesame	No	No
Soybeans and their products	No	No
Tree nuts (almonds, hazelnuts, walnuts, brazil nuts, cashews, pecans, pistachios, and macadamia nuts)	No	No
Sulphur dioxide and sulphites (10 mg/kg or more)	No	No

The above-mentioned allergens and their derivatives are known to cause an allergic reaction as listed in Annex II of the EU Food Information for Consumers Regulation No. 1169/2011. Based on our available data and information we have indicated by “Yes” or “No” whether or not a component is known to be present in the products.

We herewith declare that EuroVanillin Pure products are produced by chemical synthesis and do not contain any additives. None of the substances listed in Annex II of Regulation (EU) No. 1169/2011 and its subsequent amendments, are expected to be present in the products.

Appropriate measures are undertaken within the framework of the HACCP management (equipment cleaning, disinfection, separate storage of raw materials containing allergens) to minimise the risk of cross-contamination. Borregaard undertakes regular food safety training of its employees that includes food allergen awareness.

Microbiological content

Determination of microbial contamination of the product is done by using known recognised analytical methods. Every batch is controlled for physical properties as colour, odour and purity. The production is routinely tested on a random selection of batches twice a year.

Analysis	Maximum expected level	Method
Aerobic (total) plate count	< 100 CFU/g	NMKL 86
Coliform bacterial 37°C	< 1 CFU/g	AFNOR 3M 01/02-09/89B
Escherichia coli	< 10 CFU/g	3M 01/8-06/01
Salmonella	Absent/25 g	BACGenePCR/ AFNOR EGS 38/01-03/15*
Yeasts	< 10 CFU/g	NMKL 98
Moulds	< 10 CFU/g	NMKL 98

NMKL: Nordic Committee on Food Analysis

*These are equivalent methods.

With a very low water activity (< 0,20 aw) and pH 4,6-5,3 the Pure products are not reasonably likely to support foodborne pathogen growth even when products are held at optimum growth temperature. Therefore, the microbiological content is analysed twice per year.

Mineral and heavy metal content

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are sampled and analysed for other parameters, as minerals and heavy metals, twice a year. The analyses reports are available upon request. The products are also screened for pesticide contamination by using LC/MS/MS and GC/MS. The levels comply with regulatory requirements in the general food law. The limit of detection (LOD) and the limit of quantification (LOQ) for the methods are below the expected values.

Minerals	Maximum level	Method
Calcium (Ca)	0.10 %	ICP-MS
Phosphorus (P)	0.04 %	ICP-MS
Chloride (Cl)	0.01 %	Ion selective electrode
Sodium (Na)	0.01 %	ICP-MS
Iodine (I)	0.001 %	EN 15111
Metals, pesticides	Maximum level	Method
Lead (Pb)	< 1 ppm	ICP-MS
Copper (Cu)	< 0.5 ppm	ICP-MS
Cadmium (Cd)	< 0.5 ppm	ICP-MS
Arsenic (As)	< 0.05 ppm	ICP-MS
Mercury (Hg)	< 0.05 ppm	ICP-MS
Screening of pesticides	LOQ	LC/MS/MS and GC/MS

ICP= Inductively Coupled Plasma

The mineral, heavy metal and pesticide content is analysed twice per year.

Solubility

Approximate solubility g/l unless otherwise stated.

Temperature (°C)	0	5	10	15	20	25	30	35	40	50	80
EuroVanillin Supreme EuroVanillin Regular											
Water		3		5		10					50
Ethanol 5%							10		25		
Ethanol 10%				7	13	18	25	37	61		
Ethanol 15%							25		110		
Ethanol 20%				17	26	38	63	119			
Ethanol 25%					35		120		560		
Ethanol 50%	60		150		370		530		700		
Ethanol 70%	200		280		430		625		780		
Propylene glycol 20%							30		70		
Propylene glycol 40%					30		100		320		
Propylene glycol 60%	50		70		110		260		610		
Propylene glycol 80%	80		140		210		360		650		
Propylene glycol 100%	80		140		220		360		700		
Glycerine 10%	4		5		9		15		27		
Glycerine 20%	4		6		10		17		30		
Glycerine 50%	6		9		15		24		45		
Glycerine 70%	9		12		19		32		57		
Soy bean oil (g/kg)		12	12		18					36	
Peanut oil (g/kg)						17					
EuroVanillin Aromatic											
Water					2				8	10	
Ethanol 95%					420		500				
Propylene glycol						180			500		

FSMA compliance

Borregaard requires manufacturers of vanillin products to hold Food Safety System Certification recognised by GFSI, or to demonstrate Food Safety System practices at such level.

Borregaard AS maintains an FSSC 22000 certification for the manufacture of vanillin in Sarpsborg, Norway. The Borregaard Sarpsborg Food Safety Management System Manual includes the description of the system for establishing Food Safety Plans and includes assessment of threats (defense) and vulnerability (fraud).

Borregaard supplies customers in the USA and has assessed the relevant requirements introduced with the Food Safety Modernization Act.

- Current Good Manufacturing Practices are followed
- Trained Food Safety Team Leaders, acting as Preventive Controls Qualified Individuals are available
- A Food Safety Plan is implemented, and includes assessment of the following elements,

1. Hazard Analysis
 2. Preventive Controls
 3. Recall Plan
 4. Monitoring, Verification, Validation
 5. Corrective Actions
- A Supplier Verification Program is implemented

Food fraud

Food fraud prevention is a part of FSSC 22000 requirements and therefore this topic is taken into account by Borregaard that are certified according to the FSSC 22000 scheme.

All policies, procedures and records are included in a food fraud prevention plan ongoing by Borregaard.

The main steps are:

- **Documented vulnerability assessment** on materials, suppliers and existing control measures that:
 - Identifies potential vulnerabilities,
 - Develops control measures to reduce or eliminate the identified vulnerabilities,
 - Prioritises control measures against the identified vulnerabilities.
- **Impact assessment**, to determine the potential risk of a food fraud event.
- **Mitigation plan** to reduce food fraud risk. The vulnerability to food fraud is mitigate through the topics below:
 - Raw materials specifications
 - Analytical surveillance
 - Supplier relationship
 - Supplier audit
 - Supply chain transparency and simplification

The food fraud plan has been prepared using a predefined structured process approved by Borregaard management and the plan is revised annually.

Food defence

Borregaard maintains a scheme to protect products and production processes from intentional harm, including from vandalism, sabotage, and terrorism.

Borregaard has established **requirements for suppliers and manufacturers of products**.

- Suppliers hold appropriate permits from authorities for operation/service provided.
- Manufacturers of products hold GFSI acknowledged Food Safety Certifications. In lack of such certificates, manufacturers will be audited by Borregaard.
- Warehouses hold appropriate permits from authorities for food storage.

The food defense plan includes maintenance and review of,

- Emergency Preparedness and Response Procedures
- Execution of, and learning from exercises
- Procedure for reporting of observations, and for implementation of verified corrective action
- Procedure for Change Management
- Programs put in place as measures to protect products and production processes

The food defense plan has been prepared using a predefined structured process approved by Borregaard Management. Potentials have been carefully analysed, risks quantified, and measures put in place where found necessary.

The food defense plan complies with applicable legislation and is revised annually.

Foreign object control

In the production of the EuroVanillin Pure products there are several critical control points (CCPs) that ensure the products are free from foreign contaminants.

EuroVanillin Supreme:

- A glass and hard plastic policy with specific procedures and periodical inspections.
- A sieve with a screen size of 840 µm (20 mesh) is in place before packaging.
- A metal detector that checks the boxes before they are palletised. The metal detector has a sensitivity of 3.0 mm for non-Fe, 3.0 mm for stainless steel and 2.5 mm for Fe.

EuroVanillin Aromatic:

- A glass and hard plastic policy with specific procedures and periodical inspections.
- There are magnets and a sieve with a size of 2 mm in place before the filling point.
- An in-line metal detector is in place between the hopper and the box filling point. It has a sensitivity of 1.5 mm for Fe and 2.0 mm for non-Fe and SS.

- A metal detector is in place to check the packaged boxes before palletisation. It has a sensitivity of 5.0 mm for Fe, non-Fe and SS.

EuroVanillin Regular:

- A glass and hard plastic policy with specific procedures and periodical inspections.
- A magnetic suction device is in place before packaging.
- A sieve with a screen size of 840 µm (20 mesh) is in place after the magnetic suction device.
- A metal detector that checks the boxes before they are palletised. The metal detector has a sensitivity of 3.0 mm for non-Fe, 3.0 mm for stainless steel and 2.5 mm for Fe.

The above mentioned CCPs ensures that the products are free from foreign contaminants providing the packaging is intact.

REACH (Regulation (EC) 1907/2006)

It is hereby confirmed that vanillin (CAS no. 121-33-5) and ethyl vanillin (CAS no. 121-32-4), as manufactured and supplied by Borregaard AS, are registered under REACH:

- EuroVanillin Supreme and Regular (vanillin): 01-2119516040-60-0001
- EuroVanillin Aromatic (ethyl vanillin): 01-2119958961-24-0001

Chemicals of concern under REACH are listed on:

- The Candidate List of substances of very high concern for Authorisation (published in accordance with Article 59(10) of the REACH regulation)
- Annex XIV; List of substances subject to authorisation
- Annex XVII; Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures, and articles

All substances on these lists are not regularly monitored during the manufacture of our products. It is however very unlikely that these substances are formed during production or are contained at significant levels in our raw materials.

We would therefore state that according to our best knowledge, EuroVanillin products do not contain substances of very high concern (SVHC) in a concentration above 0.1 % w/w.

Residual solvents

The EuroVanillin Pure products have a low level of residual solvents and are controlled by testing according to a predefined test plan in accordance with the guidelines for flavours and halal requirements.

EuroVanillin Supreme:

- Toluene: Not more than 1 ppm
- Propane-2-ol (IPA): Not more than 250 ppm

EuroVanillin Aromatic:

- Ethanol: Max. 0.05%.

EuroVanillin Regular

- Toluene: Not more than 1 ppm
- Ethanol: Not more than 1 ppm

Polycyclic Aromatic Hydrocarbons (PAHs)

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic do not contain Polycyclic Aromatic Hydrocarbons (PAHs).

Pesticide, mycotoxin (aflatoxin etc.), and dioxin

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are subject to thorough analyses and there has never been found any detectable levels pesticides, mycotoxins (as e.g., aflatoxin), or dioxins. The pesticide content of the products is tested twice a year and the analyses report is available upon request.

TSE/BSE

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic do not contain protein banned by Regulation (EC) No. 999/2001 (last amended by Reg. (EC) No. 1292/2005) concerning certain protective measures regarding transmissible spongiform encephalopathies (TSE/BSE) and feeding of animal protein. This conformation is valid until revocation. Borregaard AS will inform the customer immediately if in the future changes are introduced to the manufacturing processes which affect the certified TSE/BSE status of the products.

Proposition 65 status

The Safe Drinking Water and Toxic Enforcement Act of 1986, better known as Proposition 65, are administered by The Office of Environmental Health Hazard Assessment (OEHHA).

Proposition 65 establishes a list of chemicals which the state of California's risk assessment process has determined to present a risk of cancer or reproductive toxicity.

EuroVanillin Supreme and Regular consists of vanillin (CAS no. 121-33-5) and has a purity (GC) of min. 99.9% (on dry basis). EuroVanillin Aromatic consists of ethyl vanillin (CAS no. 121-32-4) and has a purity (assay) of min. 99.9% (on dry basis).

All substances on the Proposition 65 list (last updated September 13th, 2019) are not regularly monitored during the manufacture of Borregaard's products.

It is hereby stated that according to the best of our knowledge these substances are not contained, or are contained at negligible levels, in EuroVanillin Supreme, EuroVanillin Regular and EuroVanillin Aromatic from Borregaard.

GMO

Borregaard AS declare that EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic:

- Are manufactured in a manner where neither genetic modification technology nor genetically modified ingredients are used throughout the entire manufacturing process.
- Do not have to be labelled as GMO or containing GMO materials according to **Regulation (EC) No. 1829/2003** and **Regulation (EC) No. 1830/2003**, which authorises and regulates labelling and traceability of GMO and food derived products.

Borregaard is committed to providing GMO-free products. All the products we supply are manufactured, packaged, and labelled pursuant to the producers and standards set forth above.

Ionising radiation

Borregaard AS herewith confirm that the product integrity of EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are assured through manufacturing policies, including process HACCP evaluations, and process control mechanisms. These policies and processes cover all stages of product manufacture from raw material to through to finished product storage and customer delivery.

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic have not been subjected to ionising radiation treatments as defined by **CFR 179.25** and **EU 1999/3/EC** during the manufacturing processes.

Nano particles

Borregaard AS declare that EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic do not contain nano materials and are not produced in the form of nano particles and follow the guidelines in **EU 696/2011**.

Phthalates and plasticisers

Borregaard AS hereby confirms that EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic do not contain any phthalates or plasticisers, eg. DEHP, DINP, DNOP, DIDP, DBP, BBP, DCHP, diphenyl phthalate, DNP, DBEP, BMPP, DBEP or BPA.

Nitrosamines

Nitrosamines are not regularly monitored during the manufacture of our products. According to our general knowledge about our EuroVanillin Pure products, it is unlikely that such substances are formed during production or are contained at significant levels in our raw materials.

Borregaard AS therefore claim that, according to the best of our knowledge, EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are not a potential source of nitrosamine impurities in the manufacture of pharmaceuticals.

Palm oil

Borregaard AS hereby confirms that EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic do not contain any palm oil or ingredients originating from palm oil.

Alcohol

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic do not contain alcohols, nor is alcohols used in the manufacture of the products.

Vegetarian and vegan

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic can be considered vegetarian and vegan according to all relevant definitions and interpretations of the terms vegetarian and vegan. The products are suitable for vegetarian and vegan diets.

WADA

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are not listed as prohibited substances by the World Anti-Doping Agency.

Non-animal origin

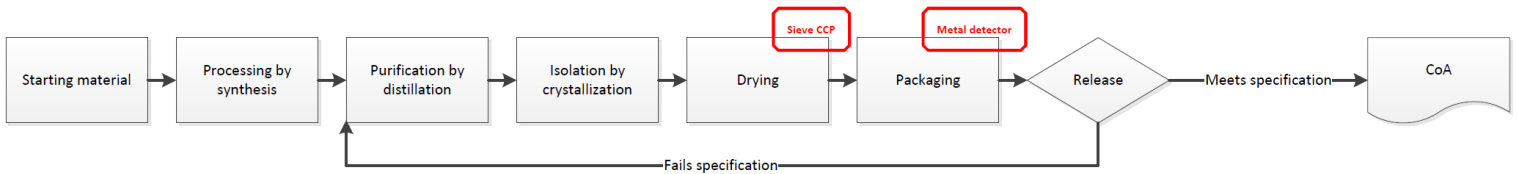
EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic have been chemically synthesised and do therefore not contain any animal or cell structure derived products. Nor are they derived from any animal or cell structure derived products.

Animal testing

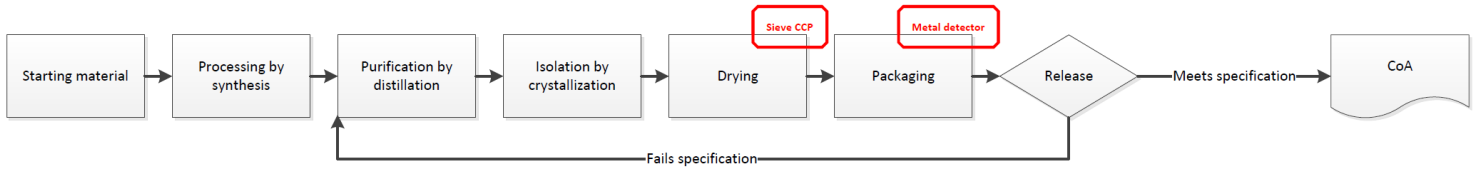
EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are not subject to animal testing, and animal testing is not part of the analysis performed on the products.

Manufacturing processes:

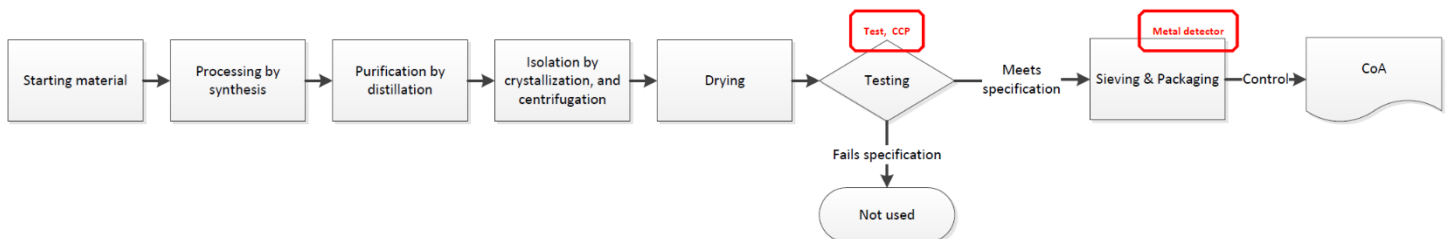
MANUFACTURE OF SUPREME



MANUFACTURE OF AROMATIC



MANUFACTURE OF REGULAR



Packaging

The EuroVanillin Pure products are packaged as follows: An inner heat-sealed PE bag containing 25 kg of product placed in a cardboard box sealed with tamperproof logo tape. The packaging material used is approved for food contact conforming to all relevant regulations worldwide. There are 16 boxes and 400 kg of product per pallet (Supreme and Regular) or 12 boxes and 300 kg per pallet (Aromatic). For milled products (Supreme FML and Regular FMG) there is 15 kg of product per bag/box and 240 kg of product per pallet due to the lower density of the products.

Description	Composition	Weight	Dimensions	Number of units per pallet
Cardboard box (Supreme and Regular)	Kraft paper	918 g, 855 g	30x40x30 cm 38,3x41,5x27,1 cm	16
Cardboard box (Aromatic)	Kraft paper		39x39x47 cm	12
Label	Paper	2 g	23,9x15,4 cm	16 (Supreme and Regular) 12 (Aromatic)
Pallet	Wood	13 kg	120x80x13,5 cm	1, one way, new
Film	PE	850 g		1
Tape		15 g		16 (Supreme and Regular) 12 (Aromatic)
Kraft underlayer	Kraft paper	310 g	115x75 cm	1
Inner plastic bag	PE, heat sealed (Supreme and Regular) or sealed with red zip tie (Aromatic)	130 g	38x105 cm	16 (Supreme and Regular) 12 (Aromatic)

Packaging food contact

EuroVanillin Supreme, EuroVanillin Regular and, EuroVanillin Aromatic are packaged in material approved for food contact, conforming to the following regulations:

- Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.
- Regulation (EU) No. 10/2011 on plastic materials plastic materials and articles intended to come into contact with food and its subsequent amendments.

Traceability

The EuroVanillin Pure products can be traced both up- and downstream by way of their batch numbers. The traceability is tested minimum once per year with mock recalls.

Batch numbers can be decoded as follows:

NXXXXX-YYQPBBBB SAP Material number

NXXXX	N= 1 indicates that the material is a finished product
X	N= 2 indicates that the material is a semi-finished product
YY	The two last digits in the year of manufacture
QQ	States the quality (“FC”, “FB”, “FE” etc.)
P	Type of product
BBBB	Serial number from 0001 to 9999 <u>per product quality</u> , independent of year

Example: 100696-20FCL1991

100696: SAP number

20: Year of manufacture

FCL: Product code

1991: Batch number

Hygiene and cleaning management

There are written instructions regarding health and personal hygiene and food safety rules (especially in clean packaging area) available.

Hygiene and internal audits are performed in critical areas, including the packaging areas, with a defined frequency according to Borregaard's internal procedures. The operators are trained on personal hygiene rules and refreshing courses are held on a regular basis.

There are cleaning and sanitising procedures in place. The cleaning products that are used are food safe and appropriate for the applications. The cleaning monitoring programs include equipment, walls, floors, and surfaces which the products may come in to contact with. Their effectiveness is checked. Records are kept.

Environmental monitoring studies have been completed and performed regularly (on specific equipment and devices in contact with the operators).

Disclaimer

The information contained in this document is given in good faith based on our current knowledge. It is only an indication and is in no way binding, particularly as regards infringement of or prejudice to third party rights through the use of our product. We only guarantee that our products comply with our sales specifications and make no other representation or warranty of any kind. This information must on no account be used as a substitute for necessary prior tests, which alone can ensure that a product is suitable for a given use. Users are responsible for ensuring compliance with local legislation and for obtaining the necessary certifications and authorisations. The labelling, substantiation and decision making of all claims for your products is your responsibility. We recommend you consult regulatory and legal advisors familiar with all applicable laws, rules, and regulations prior to making labelling and claims decisions. Users are requested to check that they are in possession of the latest version of this document, and we are at their disposal to supply any additional information.



Borregaard