

This declaration complies to the following products from

MILEI GmbH, Kemptener Strasse 91, 88299 Leutkirch im Allgäu:

<p>Whey proteins <i>Milei[®] 35, Milei[®] 35 HS Milei[®] 60, Milei[®] 65, Milei[®] 70, Milei[®] 70 A, Milei[®] 70 HPL, Milei[®] 75, Milei[®] 75 HS, Milei[®] 80, Milei[®] 80 HS, Milei[®] 80 L, Milei[®] 80 MP</i></p>	<p>Isolates from whey/milk <i>Milei[®] 90, Milei[®] 90 L, Milei[®] 90 M</i></p>	<p>Milk proteins <i>TMP 70, TMP 80, TMP 85, TMP 85 L</i></p>
<p>Micellar caseins <i>Milei[®] MC 80, Milei[®] MC 88</i></p>	<p>Milk/whey permeates and whey products <i>Lactose (unmilled, 100 mesh), Molkolac[®], Milkolac[®], Milei[®] MCA, Milei[®] 13 HH, Sweet Whey Powder</i></p>	<p>Lactoferrin <i>MLF-1, MLF-1 M, MLF-1 S</i></p>

I. Legal Conformity

We confirm compliance with the following legal regulations, guidelines and recommendations (including amendments) for the raw materials used and products made from them:

a) General Regulations

Reg. (EC) No. 178/2002	Reg. (EC) No. 853/2004	Reg. (EC) No. 1333/2008	LMBVV
Reg. (EC) No. 852/2004	Reg. (EC) No. 2073/2005	Milcherzeugnis-VO	Reg. (EU) No. 1169/2011
Reg. (EU) No. 2023/915	Reg. (EC) No. 396/2005	Kontaminanten-VO	LFGB
Reg. (EU) No. 2017/644	Reg. (EU) No. 37/2010	Reg. (EU) No. 609/2013	Reg. (EU) No. 2016/127
Reg. (EU) No. 2019/1871	Reg. (Euratom) 2016/52	Reg. (EU) No. 2015/2283	

b) Packaging material Regulations

Reg. (EC) No. 1935/2004	Reg. (EC) No. 2023/2006	Reg. (EC) No. 94/62	Bedarfsgegenstände-VO
Reg. (EU) No. 10/2011			

c) Special Regulations: National food safety standard of the People's Republic of China

GB 25595-2018 Food Safety National Standard for Lactose	GB 11674-2010 Food Safety National Standard for Whey powder and whey protein powder	GB 1903.17-2016 Food Safety National Standard Food Nutrition Enhancer Lactoferrin
The used test methods are based on ISO and European Regulations.		

d) Certifications

Certification:	Certification Body:	Valid until:
FSSC 22000 Version 5.1	TÜV Süd	2025-05-23
Halāl	Halāl Control HFFIA	2024-01-12 2024-01-31
Kosher	Orthodox Union	2024-12-31
ISO 50001:2018	DQS CFS GmbH	2025-07-14
Sedex	Intertek Certification	Reference: ZS1033340 Last audit date: 06.-08.03.2023
VLOG (GMO free)	TÜV Süd	2024-12-31

II. Declaration of Origin of Raw Materials

As manufacturer of milk and whey products for infant formula, quality is our highest priority throughout the whole supply chain. Therefore, MILEI demands high quality standards also of its suppliers and makes sure that the raw materials are sourced from countries which underlie a systematic and official control. Furthermore, we regularly demand veterinary health certificates from our suppliers' authorities.

We hereby confirm that the raw materials skim milk and whey used for manufacturing of the MILEI GmbH products originate exclusively from countries which are Member States of the European Union (EU). Skim milk and whey are made of milk solely from dairy cows (bovine).

The raw milk that is processed into MILEI GmbH raw materials whey or skimmed milk comes from the following countries:

Raw material for Skim milk	Raw material for Sweet Whey
Germany (DE) France (FR) Netherlands (NL) Austria (AT) Czech Republic (CZ) Denmark (DK) Lithuania (LT) Estonia (EE) Latvia (LV)	Germany (DE) France (FR) Netherlands (NL) Austria (AT) Czech Republic (CZ) Belgium (BE) Poland (PL)

Accordingly, the milk which is being processed at our raw material suppliers originates from Member States of the EU.

The processing takes place in Germany.

III. Conditions of Use

a) Purpose of use

The products manufactured by MILEI GmbH are intended for further processing in the food industry for later human consumption of the final product.

b) Shelf life of the products

The specified data of the shelf life are subject to the correct storage conditions and are packed in original packaging.

Product:	Shelf life:
Lactose eg unmilled, Lactose eg 100 mesh, Lactose eg W unmilled, Lactose eg 100 W, MLF-1	3 years
Milei® 35, Milei® 35 HS, Milei® 60, Milei® 65, Milei® 70, Milei® 70 A, Milei® 75, Milei® 75 HS, Milei® 80, Milei® 80 HS, Milei® 80 L, Milei® 90 M, Milkolac®, Molkolac®, Sweet Whey Powder, TMP 80, MLF- 1S, MLF-1 M, Milei® MCA, Milei® 90, Milei® 13 HH, TMP 70	2 years
Milei® MC 80, Milei® MC 88, TMP 85, Milei® 80 MP, Milei® 70 HPL	18 months
TMP 85 L, Milei® 90 L	12 months

c) Storage conditions

In order to best preserve the microbiological and chemical-physical properties of our products, the following storage conditions must not be exceeded:

- Maximum temperature: 25 °C
- Maximum relative humidity: 65 %

Bags and Big Bags shall not be exposed to direct sunlight or strong odours. Pallets shall not be stacked on top of each other.

d) Applicable documents

This Declaration of Conformity applies in connection with the respective product specification of MILEI GmbH. If information in this Declaration of Conformity deviates from data in customer specifications, the respectively valid version of the customer specification applies. The remaining parts of this document remain valid.

IV. Further Explanations

a) Nanomaterials

We confirm that in our production process nanotechnology is not used according to Regulation (EU) No. 1169/2011.

b) GMO

The above (page 1) mentioned products, except MLF-1, MLF-1 M and MLF-1S, are certified according to VLOG standard (Non-GMO production and certification standard) and therefore GMO free.

We confirm that all products delivered by us comply with the requirements for „no obligation for labelling“ according to the following regulations:

- Regulation (EC) No. 1829/2003 on genetically modified food and feed
- Regulation (EC) No. 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

c) Infant Formulae

The products Lactose eg, Whey Protein Concentrates in Nutrition Quality and Lactoferrin are foodstuff and can be used in the manufacture of infant formulae. Please note that maximum levels for certain contaminants/pesticides laid down in Regulation (EC) No. 2023/915 as well as in Regulation (EU) No. 609/2013 refer to the infant formulae ready to use (marketed as such or after reconstitution as instructed by the manufacturer) and not to ingredients.

d) Environmental Monitoring

We confirm that an environmental monitoring program is implemented on our production site. Samples from various locations are analysed for *Enterobacteriaceae*, *Salmonella spp.* and *Cronobacter sakazakii* on a regular base. The frequency of sampling varies depending on the equipment and the location.

e) Sucrose, Fructose, Beta-Carotene, (Ethyl-)Vanillin and Gluten

We confirm that in our production process the addition of sucrose, fructose, beta-Carotene and (ethyl-) vanillin is not conducted. Since our products are made from natural whey, the presence of the substances mentioned above is not to be expected.

Since beta-Carotene is naturally present in milk, which is used for cheese production, a carry-over of beta-Carotene to the whey rising from cheese production cannot be excluded.

We also confirm that all products produced by MILEI GmbH are free from gluten. In accordance with the Regulation (EU) No. 609/2013, they could be labelled as gluten-free.

f) Pesticides and Contaminants

As manufacturer of food products, we are obliged to comply with the legal limits regarding residues and contaminants according to Regulation (EC) No. 396/2005 and Regulation (EU) No. 2023/915 and its later amendments. For this reason, all our products are analyzed according to our monitoring program at least once a year for residues and contaminants by an external laboratory.

The monitoring program includes the following residues and contaminants: pesticides, dioxins, PCBs and dioxin-like PCBs, halogenated hydrocarbons, polycyclic aromatic hydrocarbons, inhibitors and veterinary drugs, melamine and cyanuric acid, heavy metals, radioactive substances, chlorate and perchlorate, Aflatoxin M1, quaternary ammonium compounds, pathogens, per- and polyfluoroalkyl substances (PFAS), mineral oil saturated hydrocarbons (MOSH), mineral oil aromatic hydrocarbons (MOAH), ethylene oxide and three GMO markers.

g) World Anti-Doping Agency (WADA)

We confirm that all our products are produced from the raw material sweet whey, respectively skim milk. They are used for further processing in the food industry.

We do not handle prohibited substances that appear on the current WADA list.

As far as reasonably possible, a contamination with banned substances at MILEI GmbH can be excluded.

Nevertheless, we cannot completely exclude an unintended input by our raw materials.

h) Food Defense and Food Fraud

We confirm that we have taken the following measures for Food defense and Food fraud:

- Responsible persons are trained
- Internal audits are carried out
- Risks are analysed and evaluated to define and remove hazards
- Critical areas are defined and protected against unauthorized entering (key system)
- An alert system is described and introduced
- A camera system and a fence around the plant are installed
- Obstruction and corruption are prevented and detected by internal measures and arrangements
- Staff is trained to report abnormalities
- A visitor management is implemented

Our products are protected by a stretch film during shipment. In collaboration with trusted freight forwarders are all measures taken to prevent the influence of a sabotage or tampering of our products.

i) Plasticizers - Phthalates and Latex, Bisphenol

We confirm that during the production process at MILEI GmbH plasticizers (for example Phthalates and Latex) are not used. Our packaging material complies with current EC/EU laws (as stated in the declaration of conformity of the packaging material).

Furthermore, our packaging suppliers confirm that during the production process of their printed or unprinted packaging out of paper, with or without inliner, no bisphenol A, B, F and S and no phthalates are intentionally used. A transition of these substances into the product is therefore impossible.

j) Foreign body prevention

We confirm that we do everything possible to avoid foreign bodies.

Therefore, we have installed several sieves during the production process with different mesh sizes. In front of the filling area, we have installed an additional sifter with a mesh size of 2.0 mm and rotation magnets with a strength of minimum 8 500 Gauss on product surface.

After filling the bags and before filling the big bags, metal detectors are installed. Upon detection of a metal clip in stainless steel with a size of ≥ 2.0 mm, ferrous ≥ 1.5 mm and non-ferrous ≥ 1.75 mm, the system stops automatically and the concerned bag or big bag will be sorted out.

Thus, we can guarantee that with these activities described above there are no health risks for the customers.

k) Allergens

We confirm that the products we produce contain the following allergens according to Regulation (EU) No. 1169/2011:

Substances or products causing allergies or intolerances	Ingredient according to the recipe		No ingredient, but possible cross-contamination	
	YES	NO	YES	NO
Cereals containing gluten (namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Crustaceans and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Eggs and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Fish and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Peanuts and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Soybeans and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Milk and products thereof (including lactose)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nuts (namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Celery and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Mustard and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sesame seeds and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Lupin and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Molluscs and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

We also confirm that we do not use fragrance allergens.

Furthermore, we have taken precautions to avoid cross contamination and have a validated cleaning method that shows no cross contamination.

l) Microbiological safety

For Food Safety, we have implemented a HACCP system with a risk analysis.

We hereby confirm that our products and thus all raw material deliveries used undergo a heat treatment of at least 72°C for at least 15 seconds (pasteurization) at our suppliers, followed by a second heating to a minimum of 72°C for 15 seconds during our production process.

Furthermore, we generally check a lot of microbiological characteristics that are in accordance with Regulation (EC) No. 1441/2007 before we release a batch.

m) Products of Animal Origin

We confirm that the raw material sweet whey originates from cheese production and is therefore produced from cow's milk and processed with microbiological rennet.

n) Animal Diseases

According to our knowledge, we confirm that the raw milk that is used for the production of all our products comes from dairy farms without Lumpy Skin Disease, Brucellosis and Foot and Mouth Disease for the past twelve months.

o) Animal Testing

We confirm that we do not conduct any animal testing with our products.

p) Hormones

We confirm that the products delivered by us comply with the relevant EC and German legislation, in particular with Directive 96/22/EC concerning the prohibition of the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta-agonists. This also includes rBST.

Furthermore, we confirm that the animals from which the milk was derived have not been subject to estrogenic treatment during the 90 days prior to producing the milk for this consignment. Therefore, it is not necessary to analyze the end products regarding oestrogens.

q) BSE – TSE

We confirm that all goods delivered by us comply with Regulation (EC) No. 999/2001 of the European Parliament and of the Council of 22nd May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

Milk and milk products are considered as safe with regard to BSE/TSE according to the WHO-Fact Sheet 113 November 2000.

r) Additives and Colouring Agents

We confirm that according to the Regulations (EC) No. 1333/2008 and Regulation (EU) No. 1129/2011 no additives or colouring agents are used during production of the products delivered to the customers.

s) Traceability – Lot Number System

We confirm that the traceability according to Regulation (EC) No. 178/2002 provides the evidence on each process step.

We use a 9-digit lot number, for example 191204410. The digits 1 to 6 refer to the production date YYMMDD. The digits 7 to 9 are an internal code.

t) Preservatives

We confirm that we do not use any preservatives according to Regulation (EC) No. 1333/2008 in the manufacture of our products.

u) Irradiation

We confirm that during the production process at MILEI GmbH no UV or ionizing radiation is used.

v) Vegetarian and Rennet

We confirm that the above-mentioned products are suitable for a lacto-, respectively ovo-lacto vegetarian diet. Our products are not vegan.

The rennet that is used in the manufacture of the raw material whey is of microbiological origin.

w) Annatto-free

We hereby confirm that that in our production process the addition of colourings, such as Annatto (Annatto Bixin, Annatto Norbixin), is not conducted.

Annatto (Annatto Bixin, Annatto Norbixin) has not been used in the whole production process from the raw milk to the end products. The absence of colourings in our raw materials is also confirmed by our suppliers in the supplier specifications.

x) Benzoic acid

We hereby confirm that in our production process the addition of benzoic acid is not conducted. As benzoic acid is naturally present in milk, a possible carry-over in small amounts from our raw materials to our end products cannot be avoided.

Please also find MILEI's „Supplier Questionnaire“ for more information.

We hereby confirm that we have processed this questionnaire to the best of our knowledge.

Leutkirch, 11.12.2023



i.V. Andreas Linsenmeier
Head of Quality



i.A. Jessica Jonnas
Quality Management