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PRODUCT NAME	
PVC Films	

COMPANY INFORMATION	
Name of Supplier	Bilcare Research GmbH
Address of Administration	Radebeulstraße 1 79219 Staufen Germany
Address of Production Site 1	Radebeulstraße 1 79219 Staufen Germany
Address of Production Site 2	Schlossmattenstraße 2 79268 Bötzingen Germany

FOOD CONTACT / FOOD ADDITIVE INFORMATION – See Appendix “Grades suitable for Food contact” (page 8)	
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European Union	
1	<p>Declaration of Compliance for Food Contact: Commission Regulation (EU) No. 10/2011 and all valid amendments (replace Directive 2002/72/EC and amendments)</p>
<p>(1) COMPLIANCE CONFIRMATION with Regulation (EC) No. 1935/2004</p> <p>This film is in compliance with the Regulation (EC) No. 1935/2004 of European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs and repealing Directives 80/590/EEC and 89/109/EEC. Traceability as defined in article 17 of this Regulation is ensured by compliance with the Industrial Guidelines on traceability of materials and articles for food contact – part 4: traceability applied in the plastic chain.</p> <p>(2) ADEQUATE INFORMATION RELATIVE TO SUBSTANCES WITH RESTRICTIONS AND SPECIFICATIONS SET OUT IN Annex I AND II of the Regulation (EU) No. 10/2011</p> <p>This material is manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No. 2023/2006. This material complies with the compositional requirements set out in Chapter II – Section 1 of Regulation 10/2011 (Authorized Substances) for what is concerning monomers or other starting substances, additives excluding colorants and polymer production aids. Substances used in manufacturing of this product, which are not yet regulated by EU Directive, are risk assessed and comply with National Laws or Recommendation of the Council of Europe or article 3 of Regulation (EC) No.1935/2004.</p> <p>(3) PIGMENTS AND COLORANTS</p> <p>Pigments and colorants used are in compliance with purity criteria defined by the Council of Europe Resolution AP (89) 1. No rules have been set out yet at EU level for the risk assessment and use of colorants in plastics. Therefore, their use in Germany should remain subject to the latest draft of the BfR Recommendation IX (Federal Institute for Risk Assessment).</p>	



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(4) ADEQUATE INFORMATION RELATIVE TO SUBSTANCES WITH RESTRICTIONS IN FOOD

Specific migration limits – article 11 Regulation 10/2011

Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

This material contains some substances which are subject to a SML (specific migration limit). These substances are present in the main part of the film:

PM Ref 10120	CAS 000108-05-4	Acetic acid vinyl ester	SML=12 mg/kg
PM Ref 26050	CAS 000075-01-4	Vinylchlorid consolidated by (EU) No. 10/2011 as of 1 May 2011 QM=1 mg/kg	SML=0.01 mg/kg

Tin organic compounds in compliance with group restriction No. 10, SML(T) 0.006 [mg/kg] and/or group restriction No. 11, SML(T) 1.2 [mg/kg] expressed as tin (10/2011/EC).

(5) DUAL-USE ADDITIVES

This material contains some substances which are dual-use additives. These are:

- Titanium dioxide (CAS 013463-67-7)
- Calcium carbonate (CAS 000471-34-1)
- Fatty acids (CAS 067701-08-0)

Titanium dioxide (CAS 013463-67-7) and calcium carbonate (CAS 000471-34-1) are coming from the white pigment. Both have no restrictions. All the other dual use additives are coming from minor ingredients of the film. They are listed with quantum satis without any SML.

Only potassium phosphate is listed with a limit of 1000 mg/kg in food, which will be confirmed by the compliance of this film to the OML (overall migration limit) of 60 mg/kg, which corresponds to the limit of 10 mg/dm². The values of the OMLs are listed above.

(6) SPECIFICATIONS ON THE USE OF THIS FILM

Migration limit - Article 12 Regulation 10/2011

Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²).



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		<p>(i) type or types of food with which it is intended to be put in contact To ensure that migration requirements are met, the final migration test must be carried out on the final article in contact with the foodstuffs or using adequate food simulants for a certain time and at the temperature defined in the relevant Directives (article 18). The sample shall be placed in contact with the food simulant representing the worst of the foreseeable conditions of use as regard contact time and as regard contact temperature; the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.</p> <p>On the base of the actual knowledge, we carried out migration tests according to Annex V - Chapter 2 - Testing for specific migration of materials and articles not yet in contact with food - to ensure that this material respects the overall and specific migration requirements, using food simulants for a certain time and at the temperature defined in the Regulation 10/2011.</p> <p>(ii) time and temperature of treatment and storage in contact with the food Migration tests have been carried out on representative samples for 10 days at 60 °C: acc. 10/2011/EC which are defined as worst foreseeable use for:</p> <ul style="list-style-type: none"> - contact time 3 days < t ≤ 30 days and - contact temperature 20 °C < T ≤ 60 °C <p>To demonstrate compliance with the overall migration limit for all types of foods testing in food simulant A, B, D1, D2 shall be performed. A representative sample of the above mentioned product base film formulation has been tested against the following simulants:</p> <ul style="list-style-type: none"> ◆ Ethanol 10 % (v/v) for 10 days at temperature 60 °C (Simulant A) ◆ Acetic acid 3 % (w/v) for 10 days at temperature 60 °C (Simulant B) ◆ Ethanol 50 % (v/v) for 10 days at temperature 60 °C (Simulant D1) ◆ Vegetable oil for 10 days at temperature 60 °C (Simulant D2) <p>All results obtained are in compliance with the restrictions and specifications set out in the Regulation (EU) No. 10/2011.</p> <p>In case of usage of this film at temperature or for times differing from this test condition (e.g. thermoforming, hot-filling, storage) or when using the films in contact with foodstuffs or mix of simulants different from the above simulants used, further migration tests may be needed as indicated in the relevant regulations.</p> <p>It is in the responsibility of the manufacturer or user of the final article to ensure that migration requirements are met and to verify the organoleptic properties for the technological suitability of the final article.</p> <p>(iii) ratio of food contact surface area to volume used to establish the compliance of the material. Tests have been carried out on film samples of 1 dm² per kg foodstuff.</p> <p>Supporting documents - Article 16 Regulation 10/2011 Appropriate documentation to demonstrate that the materials from intermediate</p>
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		<p>stages of their manufacturing as well as the substances intended for the manufacturing of those materials comply with the requirements of this Regulation will be made available by our Company to the national competent authorities on request.</p> <p>This documentation contains the conditions and results of testing, calculations, including modeling, other analysis, and evidence on the safety or reasoning demonstrating compliance.</p> <p>(7) FUNCTIONAL BARRIER</p> <p>No functional barrier is used in this film.</p> <p>(8) GENERAL RECOMMENDATIONS</p> <p>By complying with the above regulations, our duty to exercise due care with regard to the suitability of the products supplied by us for use in contact with foodstuffs has been fulfilled.</p> <p>This confirmation of compliance with food contact legislation relates only to the above mentioned product and not to the finished article produced with or without addition of additives, coatings or other substances since we have no control over any materials that might be added to achieve conversion into final article or any additional processing involved or the conditions under which the final article may be used.</p> <p>Declaration of compliance need to be updated only in principle when substantial changes in the production bring about changes in the migration or when new scientific data are available in order to limit the burden to business operators.</p> <p>Nevertheless, we have no control over any materials that might be added to achieve conversion into final article or any additional processing involved. We do not have knowledge about the conditions under which the final article may be used or physical or other changes that could take place during the final use of it.</p>
2	Directive 2003/89/EC of November 2003 amending Directive 2000/13/EC (Allergenic substances)	We confirm that we do not use any allergenic substances as a constitutional ingredient in our product.

OTHER APPLICABLE REGULATIONS		
EWR Region		
3	Regulation (EC) No. 1907/2006 for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) with subsequent	<p>The REACH Regulation relates in particular to manufacturers of articles or importers and to a certain extent also downstream users of substances. Bilcare, as processor, is only subject to the information obligations with regard to REACH. But not the registration obligations. We take this information obligation very seriously. Accordingly, we inform our customers unsolicited on the existence of candidate substances in our products as defined by Art. 33 I REACH.</p> <p>The Candidate List published on the following website:</p>



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	amending Regulation	<p>http://echa.europa.eu/web/guest/candidate-list-table is expanded as is known in June and December each year.</p> <p>We hereby certify that none of the above mentioned substances of the current SVHC candidate list are included as intentional constitutional ingredient in the production of our films in a concentration above 0.1 % (w/w).</p> <p>Should expansions in the next amendment arise we will fulfill our duty to supply information.</p> <p>Bilcare used in the manufacture of its products no substances on the authorization list in Annex XIV of REACH - Regulation listed or not without proper authorization.</p> <p>Bilcare considered in the manufacture of its products the most current restriction listed in Annex XVII of REACH - Regulation.</p>
4	2011/65/EU - RoHS-Directive	<p>We confirm that lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), including decabromodiphenyl ether are not used as raw materials in this product, nor are they added during the production process for the final product. Although we do not routinely analyse our product for these substances, we have no reason to expect that lead, mercury, cadmium, hexavalent chromium, PBB or PBDE are present in this product, except as a possible trace impurity from raw materials.</p>
5	2003/11/EC - Marketing and use of certain dangerous substances and preparations. This is a guideline for the modification of the restriction guideline 76/769/EEC	<p>We comply with the requirements of European Directive 2003/11/EC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenylether), as stated with the "Confirmation for the European Directive 2003/11/EC".</p>
6	Directive 2006/122/EC (Perfluorooctane sulfonates, PFOS); as well as of the non-use of (PFOA). This is a guideline for the modification of the restriction guideline 76/769/EEC	<p>We hereby confirm compliance with the requirements of the following EU-Directive: Directive 2006/122/EC of the European parliament and of the Council of 12th December 2006 amending for the 30th time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Perfluorooctane sulfonates). Perfluorooctane sulfonates (PFOS) have not been intentionally added for the production of our films and are not expected to be contained. Applicable concentrations limits for substances and preparations given by afore-mentioned directive, i.e. PFOS < 0.005 % are being complied with. Further we confirm that compounds of perfluorooctanoic acid (PFOA), currently not finally regulated by directive 2006/122/EC, have not been intentionally added for the production of our films and are not expected to be contained.</p>
7	2002/96/EC (WEEE)	<p>We herewith confirm that Bilcare rigid PVC films - as far as applicable - comply with the European Directive 2002/96/EC.</p>
8	DIN EN 71-3	<p>We confirm compliance with the "European standard for toy safety" (EN 71 - part 3).</p>
9	BADGE/BFDGE/NOG E-Regulation 1895/2005-	<p>We confirm that Bilcare Research follows the rules not to use any epoxy derivates (BADGE/BFDGE/NOGE - Regulation 1895/2005) as constitutional formulation parts.</p>
10	The use of material presenting risks regarding	<p>The additives used to manufacture Bilcare Research rigid PVC and PVC/PVdC-films are synthetic products derived by chemical reaction. They are in general of plant or inorganic origin. In case of animal origin our suppliers</p>




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	transmissible spongiform encephalopathies (TSEs) (EMA 410/01 Rev. 3)	have certified compliance with the current legislature and rules. We therefore do not foresee any risk in using our PVC- and PVC/PVdC rigid films and certify compliance with EMA 410/01 Rev. 3.
11	Melamines	We confirm that our rigid PVC films do not contain melamines as constitutional formulation parts.
12	Asbestos	We confirm that our rigid PVC films do not contain asbestos.
13	Bisphenol (A, E, F, S or other types)	We confirm that no Bisphenol (A, E, F, S or other types) is included in our rigid PVC films.
14	Latex-free / gluten	We confirm that our PVC, PVC/PVdC films are latex-free and gluten-free as well as gluten-lactose-free.
15	Polycyclic aromatic hydrocarbons (PAHs)	We confirm that in our PVC, PVC/PVdC films no polycyclic aromatic hydrocarbons are included respectively contained as constitutional formulation parts.
16	1-phenyleicosane- 1,3-dione (benzoylstearyl methane)	We confirm that in our rigid PVC films no 1-phenyleicosane- 1,3-dione (benzoylstearyl methane) is included as constitutional formulation part.
17	Diethylhexyl phthalate (DEHP)	We confirm that in our films no phthalate is included as constitutional formulation parts or any other kind of phthalate plasticizer as constitutional additives.
18	Recyclable	Bilcare hereby confirms that all Bilcare PVC films are fully recyclable. By this we mean that granulated Bilcare PVC films can be re-processed with adequate equipment. All produced Bilcare PVC films do not contain any recycled material from outside sources.
19	Heavy Metals	The requirements of Directive 94/62/EC (amendments 2004/12/EC and 2005/20/EC included) are met regarding heavy metals.
20	Noxious/Hazardous substances	Ensuring the conformity with EN 13695-2.
21	Energy recovery	Ensuring the calorific gain for functional unit-packaging EN 13431:2005.
North America Region / United States		
22	GMO (Genetically Modified Organisms)	We confirm that Bilcare Research do not incorporate any GMO (Genetically Modified Organisms) in their formulations.
23	ISPM No. 15 (Regulations of Wood Packaging Materials in International Trade)	Hereby we confirm that any wooden pallets used at our facility are heat treated wood pallets (in accordance with the International Standards for Phytosanitary Measures ISPM No. 15 "Regulations of Wood Packaging Materials in International Trade"). We ensure that no chemical treatments are used at any stage of the pallet manufacturing process and appropriate procedures are either in place or being developed to control wood pallet use and storage.
Other		
24	DIN EN ISO 9001:2015, DIN EN ISO 14001:2015	We are in compliance with the requirements of the DIN EN ISO 9001 and DIN EN ISO 14001 documented in our Integrated Management System (IMS). In relation with these management systems we secure our quality from raw material to finished product. Important inline controls for our films are the collection of the thickness distribution in the longitudinal and transverse direction, both on the calendar as well as at the refinement unit. This is the guarantee for perfect flatness and winding quality. Our inspection system which detects holes and their position is a very important inprocess control during the calendaring process. Depending on their



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		size the holes will be removed during the cutting process afterwards. Other important measurements during production are shrinking position measurements defined in the longitudinal and transverse direction to the mother rolls.
25	EMAS (Eco-Management and Audit Scheme)	We are in compliance with the requirements of the Environmental Management System of the European Union.
26	Section 1502 Dodd-Frank Act (Sec. 1502)	Herewith we confirm that our rigid PVC films do not contain any of the so-called "3TG"-substances (tantalum, tungsten, tin and gold) and are therefore they are "DRC conflict free".
27	Nanomaterial	Herewith we confirm that no nanoparticles are used as constituent part of our rigid PVC films.
28	Natural Rubber	Herewith we confirm that our rigid PVC films are free of natural rubber.

Comments:
This document reflects the present legal environment, based on our best knowledge as of the issue date of this letter. As we have no influence on the further processing of our films, the downstream processors have to verify the extent of our finished products for the packaging suitable for the provided product.
Should you need any further information, please do not hesitate to contact us.
Name: Simona Fecht
Title: Regulatory Affairs (RA)
Signature: 
Date: Staufen, 16.01.2019



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Appendix “Grades suitable for Food contact”
Film Grades
105 4D*
107 4D*
305 4D*
306 4D*
306 3D
315 4D*
316 4D*
304 C2
312 00
335 3A
322 00
303 3B
327 00
305 GL
305 GX
305 G0
315 GL
937 G0
937 G2
937 GX
305 3F
315 3F
937 3F

*except Surface: 304x,504x,6060