ZG 250-1

of 25 May 2021

OFI CERT Certification Basis (ZG)

Air hygiene test of FILTERS IN PASSENGER COMPARTMENTS OF VEHICLES with regard to reducing the risk of transmission of infectious agents

Basisanforderungen und Prüfungen
für die Zuerkennung des Zeichens OFI CERT

Basic requirements and tests
with regard to the right to use the OFI CERT label

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This Certification Basis will continually be adapted according to the requirements of the quality standard. Please do not hesitate to provide written input in this regard.

Note: The original of this text has been drawn up in German. The German version shall be the authentic one and prevail over the English one in all matters of interpretation and construction.
The English version shall be deemed to be only a translation for information purposes.

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1 CURRENT SITUATION – MOTIVATION, OBJECTIVES

Respiratory diseases are not only caused by particulate matter, pollutants or allergens – it is particularly viruses and bacteria that bring about a series of severe diseases of the upper and lower respiratory tracts. Epidemics and pandemics caused by influenza viruses and corona viruses have been recorded since 1918 on a worldwide scale. Notably the Spanish flu (1918), as well as the Asian flu (1957), SARS (2002) and MERS (2012), and currently COVID-19 (2019), have resulted in millions of deaths, with massive consequences for social and economic life worldwide.

However, severe diseases are not always caused by viruses: bacteria also play a relevant role: when viral infections damage the mucous membranes of the respiratory system, this facilitates the entry and reproduction of bacteria. Depending on the type of bacteria, a common cold caused by a virus can thus turn into sinusitis, bronchitis or even pneumonia. In the case of influenza, such an additional bacterial infection (secondary infection) will bring about a more severe development. *Streptococcus pneumoniae is* the most common bacterial cause of pneumonia.

Wherever groups of people are in the same room for longer periods, the risk of infections with influenza or cold viruses and bacteria rises. Whenever an infected person breathes, coughs or sneezes, thousands of infectious droplets – aerosols – are ejected. These aerosols are laden with viruses and bacteria, which are embedded in a watery coat of bronchial mucus, saliva and dissolved salts.

The use of effective air filters in ventilation systems and public/private means of transport can reduce the infection risk considerably.

This Certification Basis, including the tests and assessment criteria described herein, permits a reduction of the infection risk in public/private means of transport.

2 SCOPE OF APPLICATION

This Certification Basis ZG 250-1 applies to filters in ventilation systems that influence the quality of air recirculating in the passenger compartments of vehicles. It describes the basic requirements for passenger compartment filters without proof of a specific mode of action. For passenger compartment filters with a specific mode of action, additional requirements have been defined in the corresponding Certification Bases ZG 250-n (n: consecutive number), e.g. in ZG 250-2 relating to passenger compartment filters with biocidal surface properties. The requirements of ZG 250-1 are basic requirements that must always be met. Please contact OFI CERT for any proposals for new, or amended, Certification Bases.

In the context of this Certification Basis, the term ‘vehicle’ shall refer to:

- motor vehicles: passenger cars, lorries and buses
- rail vehicles: underground trains, commuter trains, long-distance trains and locomotives.

Reduction of the transmission risk of infectious agents

If the source of infectious agents is located in the passenger compartment, and if its ventilation system is in recirculation mode, the presence of air-borne pathogenic agents such as viral aerosols in the passenger compartment is primarily determined by the recirculation rate of the air volume in the passenger compartment by means of the ventilation system, as well as the pathogen retention capacity of the passenger compartment filter (air purification).

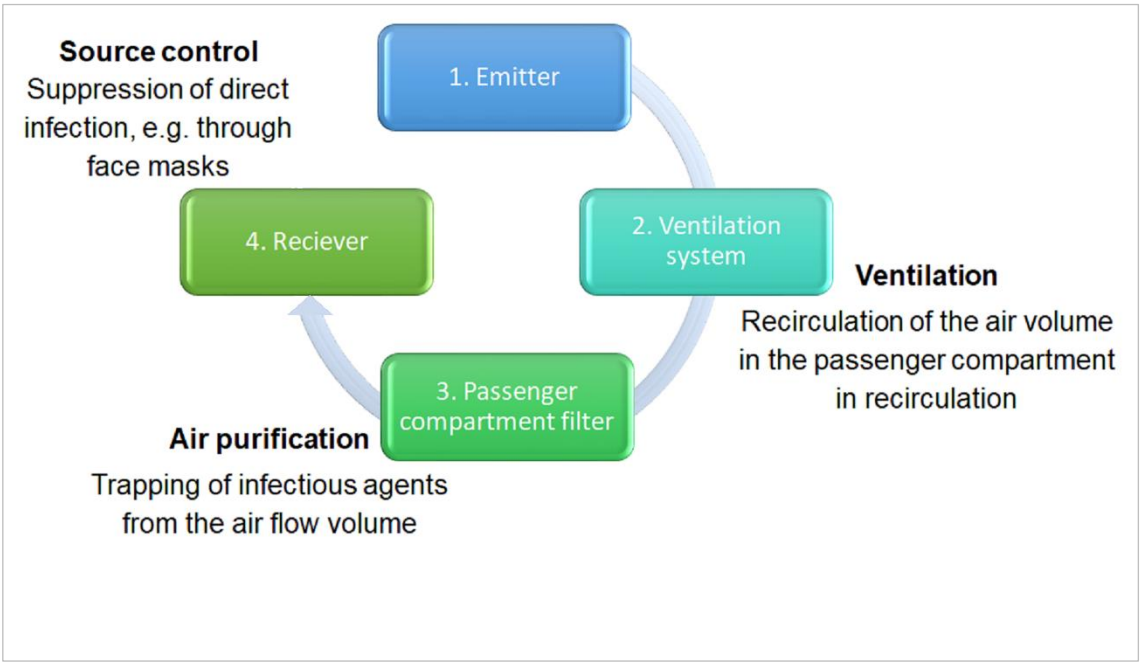

Figure 1: Transmission routes of infectious agents

The scope of application of Certification Bases ZG 250-n thus is a reduction of the transmission risk of infectious agents from the emitter (infected passenger) to the receiver (healthy passenger) through the ventilation system (infection route 1 ⇨ 2 ⇨ 3 ⇨ 4).

The direct infection route from emitters to receivers, as well as the corresponding measures to reduce the transmission risk of infectious agents by means of this route, e.g. face masks (source control) is not part of this Certification Basis and is not covered by its scope of application.

3 TESTS

The tests are based on codes of practice such as OECD guidelines, EN, ISO and DIN standards, as well as VDI standards. In addition, OFI's biologically validated test procedures (SOPs) that are relevant for the case in question are applied.

3.1 Admissible and registered ingredients

Raw materials can be classified under the Global Automotive Declarable Substance List (GADSL), listed as a REACH Substance of Very High Concern (REACH-SVHC), or covered by other statutory indications. There are 2 GADSL classifications: declarable (D) and prohibited (P). The pure substances listed in GADSL are used for assessing the material data sheet of a passenger compartment filter. The GADSL categories of biocides (GADSL) and the REACH-SVHC classification are, for instance, included in the IMDS (International Material Data System) of the automotive industry.

Proof of meeting the minimum requirements for ingredients (Table 1) can be provided, for instance, by means of an IMDS entry – submitted in writing – of the filter element to be tested (manufacturer's declaration) or by means of checks of comparable information.

Table 1: Minimum requirements for ingredients

Test item	Minimum requirements	Proof
Database entry		
Pure substances listed in material data sheet	P = Prohibited Substances with P classification: - use for certain purposes inadmissible under the relevant regulations - below the limits defined in relevant regulations.	GADSL & Biocides (GADSL) in IMDS (International Material Data System) of the automotive industry
Database entry		
Pure substances listed in material data sheet	D = Declarable Substances with D classification: - declaration obligatory in case specified limits are exceeded.	GADSL & Biocides (GADSL) in IMDS (International Material Data System) of the automotive industry
Compliance with REACH criteria		
Pure substances listed in material data sheet	Use of substances listed in REACH Annex XIV is prohibited. Restrictions and authorisations taking SVHCs into account.	(EC) No 1907/2006 Annex XIV http://echa.europa.eu/web/guest/regulations/reach/restriction http://echa.europa.eu/web/guest/regulations/reach/authorisation

If biocidal active substances are used, the goods and biocidal products treated with the said substances must, when marketed within the European Union, meet the requirements of the Biocidal Products Regulation (EU Regulation 528/2012), or when marketed outside Europe, meet the comparable regional or national legislation. In the case of marketing of products within the European Union, proof of authorisation by the European Chemicals Agency (ECHA) must be provided for all biocidal active substances of the component in question. This is a mandatory requirement, for instance, if biocidal surface properties (surface disinfecting properties) are specified in the context of the ZG 250-2 label. In addition, biocidal products must meet the applicable national and international requirements in the relevant biocidal regulations.

3.2 Tests of filter elements/composite filtration media

3.2.1 Bacterial and viral retention capacity

The filters are tested with regard to their bacterial and viral retention capacity in new condition, as well as after ageing.

Ageing of the filtration media is achieved by the following steps:

1. Store at 80 °C for 24 h.
2. Allow to cool to room temperature.
3. Store at 55 °C with 95 % relative humidity for 48 h.
4. Allow to cool to room temperature.
5. Store at -20 °C for 24 h.
6. Allow to warm to room temperature before testing.

The requirements for the filters to be tested are given in Tables 2–4.

Table 2: Requirements for bacterial retention capacity for all vehicles

Test item	Minimum requirements	Proof
Bacterial retention capacity		
Filter element (new)	> 90.0 %	OFI SOP 350.014 bacterial filtration procedure BOReAS test facility
Filter element (after ageing)	> 88.0 %	OFI SOP 350.014 bacterial filtration procedure BOReAS test facility

The requirements for viral retention capacity have been defined on the basis the viral minimum air purification efficiency determined in a circulation simulation model, with assumptions e.g. for viral pollution rates and infection limit values.

Table 3: Requirements for viral retention capacity for passenger cars and lorries

Test item	Minimum requirements	Proof
Viral retention capacity		
Filter element (new)	> 86.0 %	OFI SOP 350.012 viral filtration procedure BOReAS test facility
Filter element (after ageing)	> 80.0 %	OFI SOP 350.012 viral filtration procedure BOReAS test facility

Table 4: Requirements for viral retention capacity for buses

Test item	Minimum requirements	Proof
Viral retention capacity		
Filter element (new)	> 94.0 %	OFI SOP 350.012 viral filtration procedure BOReAS test facility
Filter element (after ageing)	> 88.0 %	OFI SOP 350.012 viral filtration procedure BOReAS test facility

The viral retention capacity of the filter element (viral filtration efficiency, VFE) is determined by means of fine aerosol particles with tracer viruses on a single filter element at a defined operating flow rate for passenger cars and lorries (200 m^3/h) as well as buses (300 m^3/h). For rail vehicles, the minimum requirements are defined in accordance with the project in question.

Since the differences between types of ventilation system in buses and rail vehicles can be considerable, it may be necessary to define, and use, deviating operating flow rates depending on the type of system.

Templates, adapter plates etc. are used to control the operating flow rate in a way that enables a defined test flow rate range.

3.2.2 Re-aerosolisation

Re-aerosolisation means that viruses that have been trapped by the filtration media are released in the purified air flow. Table 5 gives the following basic requirements for re-aerosolisation that have been defined, irrespective of the mode of action.

Table 5: Requirements for re-aerosolisation in accordance with basic requirement ZG 250-1

Test item	Minimum requirements	Proof
Re-aerosolisation (basic requirement ZG 250-1)		
Filter element (new/after ageing)	< 500 pfu* (=infection threshold) in purified air flow	OFI SOP 350.013 re-aerosolisation basic requirement ZG 250-1

*pfu… plaque forming units

For this purpose, the filter specimen is first impinged with viruses in a virus-laden air flow. After a defined retention time, virus free-air is fed to this filter sample to check whether viruses from the filter sample enter the purified air.

3.2.3 Biocompatibility

3.2.3.1 Cytotoxicity under flow conditions

Cytotoxicity tests are performed to assess cell toxicity of the composite filtration medium when air from the ventilation system flows through it. For this purpose, flow tests are performed in which fresh air flows through the composite filtration media to be tested. In flow tests, with scaling of flow rates related to the speed of the air flow through an average indoor filter at approx. 200 m³/h, the flow through the filter is tested for cytotoxicity after 8 h. This is aimed at simulating the air flow through the filter in the ventilation system, assuming a maximum daily driving time of 8 hours.

The relevant requirements are given in Table 6.

Table 6: Requirements for cytotoxicity test under flow conditions

Test item	Minimum requirements	Proof
Cytotoxicity		
Composite filtration media	Degree of cytotoxicity ≤ 2 (≤ 50 % growth inhibition)	ISO 10993-5 and 12

3.2.3.2 Irritation

The tests were performed by means of extraction of the composite filtration media

Irritation tests are performed to examine possible irritation effects of the composite filtration medium in the case of skin contact during production, exchange or mounting at the workshop (filter handling test). In addition, possible eye irritation is tested. The relevant requirements are given in Table 7.

Table 7: Requirements for the extract of the composite filtration media (irritation)

Test item	Minimum requirements	Proof
Irritation / skin tolerance		
Composite filtration media	≥ 50 %	Skin model: EpiDerm SIT Test method: Based on OECD TG 439: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method (pure substances, ground filter) and SOP of the company Mattek (IN VITRO SKIN IRRITATION TEST FOR MEDICAL DEVICE EXTRACTS). Extraction: EN ISO 10993-12 Assessment scheme: The specimen is regarded as irritating if viability decreases below 50 %.
Eye irritation		
Composite filtration media	≥ 60 %	On the basis of OECD TG 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage. Classification in accordance with UN GHS (not irritating and irritating). Assessment scheme: The specimen is regarded as irritating if viability decreases below 60 % compared to the blank.

3.2.3.3 Sensitisation

Sensitisation tests are performed to examine the allergic potential of the filter elements, which may lead to inflammation in the organism.

In the tests, the flow through the composite filtration media is examined. This is aimed at ensuring the skin tolerance of the ‘filtrating operation’ (use in the vehicle):

- test during filtrating operation.

In flow tests, with scaling of flow rates related to the speed of the air flow through an average indoor filter at approx. 200 m³/h, the flow through the filter is tested for sensitisation after 8 h. This is aimed at simulating the air flow through the filter in the ventilation system, assuming a maximum daily driving time of 8 hours. Repeated exposure (daily rides) does not increase the sensitising potential. For positive sensitisation, the threshold must be exceeded once. The relevant requirements are given in Table 8.

Table 8: Requirements for sensitisation

Test item	Minimum requirements	Proof
Skin tolerance – ARE sensitisation		
Composite filtration media	≤ 2	On the basis of OECD Guideline TG 442D: In Vitro Skin Sensitisation (Are-Nrf2 Luciferase Test Method) Extraction: EN ISO 10993-12 Assessment scheme: Reporter gene assay: Increased gene expression indicates a sensitising potential (fold luciferase induction > 2 indicates a significant induction of the Nrf2 pathway).
Skin tolerance – DPRA sensitisation		
Composite filtration media	≤ 10 %	On the basis of OECD Guideline Test No 442C: In Chemico Skin Sensitisation (Direct Peptide Reactivity Assay, DPRA) Extraction: EN ISO 10993-12 Assessment scheme: A depletion > 10 % is regarded as potentially skin sensitising (based on the internal threshold evaluation during validation).

4 LABELLING

The certificate holder shall be responsible for labelling. The manufacturer shall, as a minimum, provide the following information on the product, or at least in the product documentation:

- certificate number (e.g. 0123)
- label of certification body: OFI CERT (referred to as 'Konformitätszeichen' / conformity mark in the application for certification)
- number of Certification Basis: ZG 250-1
- optional: OFI logo.

5 QUALITY ASSURANCE

Quality assurance consists of initial testing and quality monitoring, consisting of internal inspection and third-party inspection.

5.1 Scope of initial testing

The scope of initial testing is given in Table 9.

Table 9: Scope of initial testing

Type of test	Test/requirement
Admissible and registered ingredients	Section 3.1 / testing, e.g. on the basis of IMDS entry provided in writing for each component to be tested, or on the basis of comparable information
Retention capacity, re-aerosolisation, biocompatibility	Section 3.2 / tests of the filter element or composite filtration media

5.2 Scope of internal inspection

In order to ensure a consistent high quality, components or filter elements shall be tested annually by the manufacturer, in accordance with the scope of testing given below. The test records and test specimens shall be kept for 5 years.

Table 10: Scope of internal inspection

Type of test	Test/requirement
Admissible and registered ingredients	Section 3.1/ testing, e.g. on the basis of IMDS entry provided in writing for each component to be tested, or on the basis of comparable information

5.3 Scope of third-party inspection

In order to ensure third-party inspection, a certification contract shall be concluded with OFI CERT. In order to ensure a consistent high quality, each certified filtration medium shall be tested every two years, with the following test scope:

Table 11: Scope of third-party inspection

Type of test	Test/requirement
Retention capacity (new filter element)	Section 3.2.1 / viruses and bacteria
Biocompatibility (composite filtration media)	Section 3.2.3.1 / cytotoxicity under flow conditions
Verification of internal inspection check of test reports by OFI CERT	Inspection of test records by OFI CERT

The results will be summarised in a third-party inspection report and made available to the certification body.

6 MODIFICATIONS

This Certification Basis will continually be adapted in accordance with the state of the art. Please do not hesitate to send any requests for modifications, or comments, to the OFI CERT certification body (office@ofi.at), where they will be collected and discussed by the bodies in charge.

OFI CERT shall be notified of any changes relating to the certified product (e.g. changes in raw materials, components etc.). OFI CERT will, in cooperation with the testing body, decide whether a new initial test will be required.

7 DOCUMENTS CITED

The relevant tests are carried out in accordance with (or on the basis of) the following air quality guidelines (German versions whenever available):

DIN 71460-1	Road vehicles – Air filters for motor passenger compartments – Part 1: Test for particulate filtration
ISO/TS 11155-1	Air filters for passenger compartments – Part 1: Test for particulate filtration
DIN EN 481	Size fraction definitions for measurement of airborne particles
ISO 10993-5	Tests for *in vitro* cytotoxicity
ISO 10993-12	Sample preparation and reference materials
OECD TG 349	*In Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method
OECD TG 442D	*In Vitro* Skin Sensitisation ARE-Nrf2 Luciferase Test Method
OECD TG 442C	*In Chemico* Skin Sensitisation. Direct Peptide Reactivity Assay (DPRA)
OECD TG 492	Eye Irritation Test (EIT) - Reconstructed Human Cornea-like Epithelium Method
SOP 110.027	Zytotoxizität (cytotoxicity)
SOP 350.011	Allgemeine Bedienung, Handhabung & Reinigung BOReAS-Prüfstand (general operation, handling and cleaning/BoReAS test facility)
SOP 350.012	Filtrationsverfahren Viren BOReAS-Prüfstand (viral filtration procedure/BOReAS test facility)
SOP 350.013	Re-Aerosolisierung gemäß ZG 250-1 (re-aerosolisation in accordance with ZG 250-1)
SOP 350.014	Filtrationsverfahren Bakterien BOReAS -Prüfstand (bacterial filtration procedure/BOReAS test facility)
USP 87	Biological reactivity tests, in vitro
VDI 3489	Particulate matter measurement – Methods of characterizing and monitoring test aerosols
VDI 3491	Particulate matter measurement – Generation of test aerosols
VDI 6032- 1	Ventilation and indoor-air quality in vehicles – Hygiene requirements for ventilation and air-conditioning systems