

Factory standard

Valid for
Miele

Replaces Index no.
195/04

valid from
01.06.2018

Index no.
195/05

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Author (STKZ/AKZ/Name)

GTZ/EKK/Lepel
GTZ/TPE/Rohde

Publisher (STKZ/AKZ)

GTZ/TPE/Wendker

Approved by (STKZ/AKZ)

GTZ/GL/Dr. Breit

Count of enclosures

1

Title

Restricted Substances

Summary

This factory standard describes bans and restrictions on the use of certain substances which, among other things, protect the environment and human health in the use and disposal of materials, components, accessories and finished products.

Compliance with all bans / restrictions stipulated by legislation on the use of substances and materials is expected from, and is the responsibility of, the supplier.

The legal requirements for the European Economic Area (EEA), along with any national specifications, must be complied with. Additional or alternative areas of applicability are to be specified to the suppliers.

If in cases of doubt, where further information is required regarding demarcation of areas of applicability and use, this must be proactively sought by the supplier from Miele/imperial.

Compliance with Miele factory standards does not release those responsible from their responsibility to comply with valid legislation, guidelines and regulations in full.

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1 Purpose

This factory standard describes bans and restrictions on the use of certain substances in materials, components, accessories and finished products. Suppliers to Miele/Imperial must comply with such bans and restrictions and observance of referenced reporting obligations. Contraventions compromise the validity of declarations of conformity submitted by Miele/imperial to national, European and international customers or monitoring authorities.

2 Valid for

This Miele Factory Standard applies to Miele/imperial and suppliers.

3 Possible information sources for satisfactory compliance with legal requirements

- German legislation: juris; web page of Federal Ministry of Justice and Consumer Protection
- European legislation: Web page EUR-Lex
- Non-European legislation, Legislation of states of the European Economic Area (EEA) or other states: Web page of relevant ministry or a trade association

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4 Structure

In addition to the fundamental bans and restrictions on use, bans (Point 6.1) or restrictions (Point 6.2), application-related restrictions of affected substances and materials are to be observed and/or documented; where necessary, information on this must be provided in compliance with regulations.

Application-related restrictions for:

- Materials/components, accessories and finished products intended to have contact with food or drinking water (Point 6.2.1)
- Materials/components, accessories and finished products that could be touched during intended use (Point 6.2.2)

If the extent to which the supplied materials/components, accessories or finished products are affected by any of these application-related restrictions is unclear, this must be clarified with Miele/imperial.

5 Documents that also apply

The list of other applicable documentation below does not claim to be complete. Documents are applicable inclusive of all relevant and current modifications.

- | | |
|--|---|
| I) VDE 0042-4;
IEC 62474 | Material Declaration for Products of and for the Electro-technical Industry. |
| II) GS Specification AfPS
2014:01 PAH | Monitoring and assessment of polycyclic aromatic hydrocarbons (PAH) as condition for award of GS label |
| III) PAH guideline VDE
EK 601-15 Rev1 | PAH guideline for electrical products
(Requirements from this guideline in current version considered) |

6 Fundamental bans and restrictions on use for substances

If stricter legal requirements than the bans and restrictions on use are specified, these must be observed.

6.1 Bans on use

In the interests of protecting the environment and the human health of those involved in subsequent waste treatment processes, the substances listed below must not be present in any materials, components, accessories and finished products supplied to Miele/imperial. This refers specifically to the deliberate presence or deliberate addition of these substances.

The substances listed in 6.1 may only be used if there are no substitute substances that may feasibly be used, if these substitutes are unacceptable for financial reasons, or if the use of the substances listed in 6.1 has been specified. If this is the case, their use must be

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- a) approved by the consuming department and
- b) declared in accordance with Point 7.
- c) These exceptions must be checked regularly with respect to their validity periods and any modifications. If the status changes, the declaration (in accordance with Point 7) must be updated.

The consuming departments must define and document a process for this and must archive all verifiable documentation associated with individual cases.

Use bans are valid for:

- All types of asbestos-fibre or ceramic-fibre substitutes
which are suspected to have carcinogenic potential in accordance with the internationally accepted definition given by the IARC, Lyon (International Association for Research of Cancer). <http://monographs.iarc.fr/ENG/Classification/index.php>
- Bio-persistent fibres.....
- Biocides.....
- Azo dyes
Substances which may produce nitrosamines as a result of the dissociation of azo-group amines and subsequent chemical reactions.
including compounds
in all its forms
in all its forms
or substances that react to produce nitrosamines.
- Chlorinated paraffins
- Dioctyl tin
- Dibutyl tin
- Nitrosamines
- Red phosphorous.....
If it has not been specifically chemically bound or treated with a hydrolysis-stable coating or further processed.
- Nano materials.....
that necessitate registration in a national or international register or are already registered.
- PVC.....
Cabling and wiring insulation is currently excluded. Non-PVC materials are preferable for this purpose.
- Substances in enclosure XIV REACH 1907/2006
For components, accessories and finished products that are produced outside the applicable REACH regulation area. An exception is an approval valid in the EEA.
- Crystalline silicone dioxide SiO₂.....
for use in VIPs (Vacuum Insulation Panels).

6.2 Restricted applications

In the interests of protecting the health of individuals during the use and operation of finished products, the substances listed below either must not be used in materials/components, accessories and finished products being supplied to Miele/imperial, or they must be below the specified concentrations if they are used. The maximum permissible values listed refer to the percentage by weight in the homogenous material. Application for this is in accordance with RL 2011/65/EU (RoHS). In the case of fibres, the maximum permissible values refer to the percentage by weight in the relevant material. The provisions in Section 6.2, "Restrictions on use", refer only to substances added deliberately. The entire supply chain must be taken into consideration.

The substances listed in 6.2 over the mentioned limits may only be used if there are no substitute substances that may feasibly be used or if these substitutes are unacceptable for financial reasons. If exceptions apply, it is necessary to proceed in accordance with the provisions in 6.1.

- Substances on the REACH Candidate List Max. permissible value 0.1 % by weight = 1 g/kg that are not subject to further legal regulation for use in products
- Beryllium including its compounds..... Max. permissible value 0.1 % by weight = 1 g/kg
- Tetrabrombisphenol A Max. permissible value 0.1 % by weight ... = 1 g/kg
Max. permissible value applies to freely available monomers
- Phthalate..... Max. permissible value 0.1 % by weight = 1 g/kg

6.2.1 Materials/components, accessories and finished products intended to have contact with food or drinking water.

- Bisphenol A (BP A)..... Materials intended for contact with food. Max. permissible legal value, but max. 0.1 % by weight = 1 g/kg

6.2.2 Materials/components, accessories and finished products that could be touched during intended use

- Polycyclic Aromatic Hydrocarbons Mandatory PAH maximum content for materials of relevant contact, handle and control areas that must be categorised due to risk assessment results.

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Parameters	Category 1 Materials intended for oral contact. Or materials in toys intended for prolonged skin contact (longer than 30 sec.)	Category 2		Category 3	
		Materials not covered by Category 1, with likely skin contact lasting longer than 30 sec. (prolonged skin contact) or short-term repetitive contact with human skin*	Toy acc. RL 2009/48/EC	Remaining products acc. to German Product Safety Act	Toy acc. RL 2009/48/EC
Benzo[a]pyrene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[e]pyrene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[a]anthracene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[b]fluoranthene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[j]fluoranthene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[k]fluoranthene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Chrysene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Dibenzo[a,h]anthracene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[ghi]perylene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Indeno[1,2,3-cd]pyrene mg/kg	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Acenaphthylene, acenaphthene, fluorene, phenanthrene, pyrene, anthracene, fluoran- thene, mg/kg	< 1 Total	< 5 Total	< 10 Total	< 20 Total	< 50 Total
Naphthalene mg/kg	< 1	< 2		< 10	
Total 18 PAH mg/kg	< 1	< 5	< 10	< 20	< 50

(*) Formulation of "short-term repetitive contact with human skin" from REACH Annex XVII No. 50 Addendum (Regulation (EU) No. 1272/2013)

Stricter requirements may be imposed according to specific requirements by Miele/Imperial.

7 Reporting obligations and declaration of conformity

The confirmation of the fulfilment of this factory standard in the supplier relationship management system of the purchase department always encloses the assurance of the conformity of all materials/components, accessories and finished products to be supplied to Miele/imperial conform to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 for the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

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The declaration of conformity enclosed with the Miele factory standard must be issued immediately if a material/component, accessory or finished product to be supplied to Miele/imperial

- a) contains substances listed in Point 6 and/or
- b) application-related exceptions based on legal provisions are being used and/or
- c) substances from the Candidate List in accordance with regulation EC No. 1907/2006 REACH (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp) are present and/or
- d) contain substances from the annex of so-called "Sweden tax" (Bilaga till lag om skatt på viss elektronik - Regeringen.se) in material of print circuit boards or plastic components with a weight greater than 25 grams. Information on this have to be differ in additive and reactive bound substances.
- e) contain substances from the California Proposition 65 list (www.P65Warnings.ca.gov.) that exposed to cause cancer, developmental and/or reproductive harm. In addition the kind of cause have to named.

The consuming department of Miele/imperial can fix tightening requirements on conditions for the declaration (e.g. conformity on RoHS) as well as on the scope of the declaration.

Alternatively, declarations in accordance with IEC 62474 (VDE 0042-4) that at least represent the information requirements according to this factory standard will also be accepted.

Separate updated documentation is added in the case of materials in contact with food according to Regulation (EC) No. 2023/2006 (GMP) and Regulation (EC) No. 1935/2004, and regarding materials for plastics, for example, in accordance with Regulation (EC) No. 10/2011.

The process of declaring substances and materials is designed to support communication concerning legally relevant and Miele-specific bans or limitations. For this reason, all substances that are hazardous to the environment or to health must be declared.

Enclosures

Miele Factory Standard 195/05 conformity declaration

8 Revision history

- 24.03.2010
 - Pkt. 3: 76/769 EEC deleted
 - Pkt. 4.2: Max. permissible value for dimetylfumarate in mg/kg only

- 03.11.2010
 - Pkt. 3 2007/639/EC Decision of Commission added
 - V added to REACH
 - RL added to RoHS
 - Pkt. 4.1 PCB flame retardant deleted
 - Pkt. 4.2 PCB flame retardant added

- 08.12.2011

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Summary modified

- Pkt. 1 Reference to food/potable water legislation added
- Pkt. 3 Documents that also apply
1935/2004/EC food contact deleted
10/2011/EC Plastic/material/foodstuffs deleted
ElektroG and GefStoffV (German national legislation) deleted
DIN EN ISO 1043-4 replaced by DIN EN ISO 11469
ZEK 01.4-08 PAH updated
- Pkt. 4 Modified:
- Pkt. 4.1 4.1 old und 4.2 old amalgamated
Reference to fibres added
- Pkt. 4.2 Note on avoidance of REACH candidate substances added
Dibutyl tin added
PAH table updated
DHNUP added
DIHO added
- Pkt. 5 Requirements modified
- Explanation Changes modified

07.03 2017

Comprehensive changes.

Comparison document to be consulted.

14.02.2018

- Author two deleted
- Summary 3 para. last sentences added: of Miele/imperial
- Po. 6.1 2 para. 1 sentences replaced: , in closely limit to special cases,
and added: of Miele/imperial
- Po. 6.2 3 para. inserted: Use bans are valid for:
1 para. 1 sentences parts deleted.
2 para. 1 sentences inserted: over the mentioned limits
and: or it is required by Miele/imperial
- Po. 6.2.2 Last para. last sentences added: Furthermore
- Po. 7 1 para. added: The easy confirmation of the fulfilment of this factory standard in the
confirmation system of the purchase always encloses the assurance of
2 para. added: Title
2 para. 1 sentences partly replaced: If
2 para. list added: d) substances of the "Sweden tax"
2 para. list added: e) substances of the "California Proposition 65"
3 para. deleted
New para. inserted: consuming department
New para. inserted: FCM documentation
List d9 added
Para. consuming department added