

**Regulatory  
Compliance  
Declaration  
&  
General  
Product  
Information**



2022-04-14



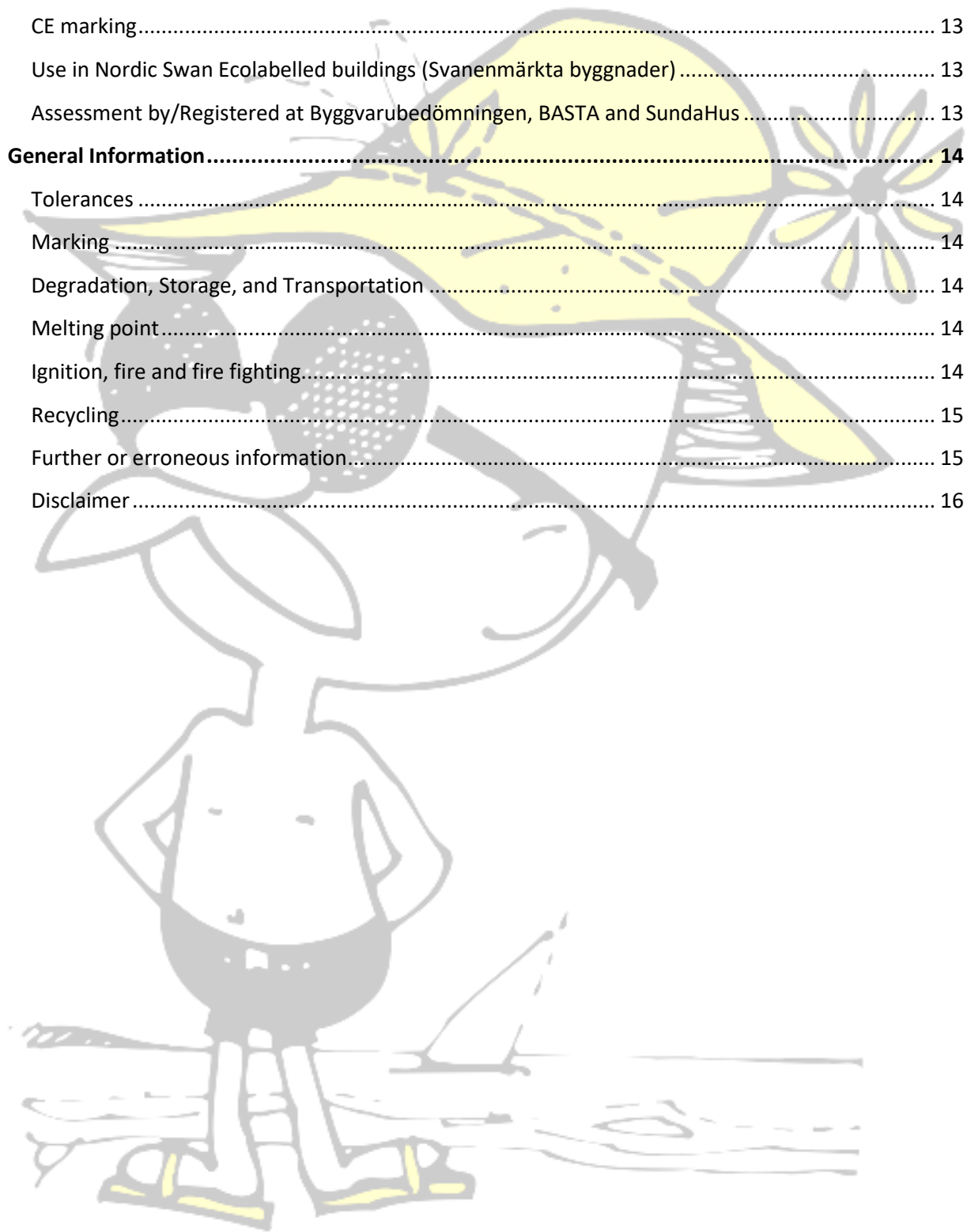
# Kullaplast AB

## Regulatory Compliance Declaration & General Product Information

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## Quality Documents from Kullaplast AB

Kullaplast AB frequently receives enquiries about our compliance with relevant legislation and many of these enquiries require an immediate response. In order to respond quickly and consistently to all our customers we have prepared this Quality Documents Compilation.

Upholding regulatory standards, including the legislative demand on transfer of information to our customers, are a principal issue to Kullaplast AB. Our aim is to maintain the highest level of service with swift, complete and uniform answers and documentation. Therefore, we have developed the following set of documents:

### *Product Data Sheets*

All our products are accompanied by a Product Data Sheet (PDS) that specifies the product and links it to this document. As the vast majority of our products are made to the customer's specifications, the PDS are not available beforehand. PDS are distributed on demand.

### *Regulatory Compliance & General Product Information*

This document. Includes extensive legal information, declarations of compliance, declaration of absence and general information together with links to sources of further information outside our organisation.

### *Certificates*

Several certificates verify that our products meet applicable legal or regulatory requirements. Please find further information under respective heading below and the certificates on our [website](#).

As a customer you will get timely answers as well as a complete list of applicable regulations, and answers to frequently asked questions about our products and their content. For customers at the wholesale level, the unified documentation also facilitates communication with your customers, since you should in many cases be able to refer directly to our documentation without having to communicate each question with us. However, since we have hundreds of customers and thousands of unique products, we are unfortunately unable to fill in your own documents regarding this information.

We believe that you understand this and that you will appreciate the benefits of the overall setup. If you have further questions you are always welcome to contact our Quality Manager, see contact information below.

## Certified Quality and Food Safety Management System

Our Quality and Food Safety Management System is certified according to ISO 9001 (Quality) and ISO 22000 (Food Safety). Certificates are available for download from our [website](#).

## Regulatory Compliance – General

Kullaplast AB produces polyethylene products for packaging and protection. These products, or the materials used in the production of the products, are subject to regulation per the Directives and Regulations listed in this document. Regarding the materials, we have received confirmations from our suppliers that their virgin materials do comply with the requirements applicable to our products. Consequently, we hereby declare that our products, made from virgin materials, complies with the regulations below, including amendments and corrections.

### REACH

According to the REACH Regulation (EU 1907/2006: Registration, Evaluation, Authorisation and Restriction of Chemicals), our products are defined as *articles*. This means “*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*”. Articles are excluded from registration according to REACH.

Regarding the chemical substances and mixtures that we use as virgin raw materials in our production we have been informed by our suppliers that they have received at least a pre-registration confirmation and a registration intention.

Substances mentioned in the REACH Regulation are covered in our [General Absence Declaration](#).

### SCIP Database

SCIP is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD). Companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market have to submit information on these articles to ECHA, as from 5 January 2021.

Kullaplast’s products does not fulfil this criterion and are therefore exempt from registration in the SCIP database.

### Material Safety Data Sheet (MSDS)

As our products are defined as articles and lack any inherent dangerous properties such as being persistent, toxic, or bioaccumulative, there is no legal obligation to set up a MSDS for our products according to the REACH (EU 1907/2006) and CLP (No 1272/2008) regulations.

### *ELV, WEEE, and RoHS*

Our products are not in scope of Directive 2000/53/EC on End-of Live Vehicles (ELV) nor Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). Thus, none of these directives, nor the Directive on the Restriction of Hazardous Substances (RoHS), applies to our products.

However, we have been informed by our suppliers that none of the virgin materials they supply to us contain any of the hazardous substances in the RoHS directive. These substances are covered in our [General Absence Declaration](#).

### *Packaging and packaging waste*

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, and specifically Article 11, requires that the maximum concentration level of Lead (Pb), Mercury (Hg), Cadmium (Cd), and Hexavalent chromium (Cr<sup>6+</sup>), present in packaging or packaging components does not exceed 100 ppm by weight.

### *Dual-use items*

To the best of our knowledge our products are not included in “Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items”, including amendments and corrections.

*Consolidated versions of the regulations above can be found in [EUR-Lex](#).*

## Declaration of Compliance – Food Contact Materials

***The DoC below is only applicable for products intended for food contact!***

In addition to the Declaration of Compliance above, which is valid for all our products, we hereby declare the compliance with the applicable sections of the following directives and regulations regarding food contact materials:

- Commission Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, including amendments and corrections.
- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, including amendments and corrections.
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, including amendments and corrections.
- Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, including amendments and corrections.
- Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food, including amendments and corrections.
- Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, including amendments and corrections.

*Consolidated versions of the regulations above can be found in [EUR-Lex](#).*

### Identification of Food Contact Materials

Products from Kullaplast AB that are intended for Food Contact have the text “Approved for direct contact with food - YES” on their Product Data Sheets.

### Use of Food Contact Materials

Food Contact Materials are intended for packaging and protection at room temperatures and below. No material or product is intended for heating, cooking, use in microwave ovens or similar. Specifications with respect to migration can be found in our Normpack certificate, see paragraph below.

### *Specific Migration Limits and Dual Use Additives*

Some of the materials used in the production of our products contain substances that are subjected to Specific Migration Limits (SML) or classified as Dual Use Additives. However, in our final products these substances are, if present at all, only present in quantities that in case of their migration does not amount to relevant contribution to exceed the limits as set in the applicable food legislation.

This have been established by the prescribed migration tests and is verified by our Normpack certificate, see paragraph below.

### *Printing inks*

The printing inks used by Kullaplast are manufactured and used according to the guidelines from the European Printing Inks Association (EuPIA), current version can be found at <http://www.eupia.org>, and are suitable for use on the non-contact side of food packaging.

### *Food Safety Information*

Please make sure that the information in this document as well as the Product Data Sheet for your specific products follow the products through the food chain, i.e. relay the information to your customers, if applicable.

### *Normpack Certificate*

This is a certificate from [The Trade & Industry group Normpack](#) that states the performed migration tests and their results. The certificate also declares which types of food the material is approved for direct contact with, as well as contact time under foreseeable use. The time/temperature conditions specified are valid with regard to migration, the physical properties of the materials may require that use is restricted to lower temperatures than those stated in the Normpack certificate. We have included a guide to the interpretation of the certificate which is available for download from our [website](#).





## Declaration of Compliance - Regulation (EU) No 10/2011

### **Declaration of Compliance as specified in Annex IV of Regulation (EU) No 10/2011**

- (1) The identity and address of the business operator issuing the declaration of compliance:  
*Kullaplast AB, Box 62, SE-26321 Höganäs, Sweden.*
- (2) The identity and address of the business operator which manufactures the plastic articles:  
*Kullaplast AB, Box 62, SE-26321 Höganäs, Sweden.*
- (3) The identity of the articles - *Please refer to the Product Data Sheet. The PDS also states if the article is approved for direct contact with food; if so, this DoC is valid for the article.*
- (4) The date of the declaration: *2022-04-14.*
- (5) Confirmation that the plastic articles meet the relevant requirements laid down in Regulation (EU) No 10/2011 and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004. – *This is hereby confirmed.*
- (6) Adequate information relative to the substances used, or products of degradation thereof, for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation. At intermediate stages, this information shall include the identification and amount of substances in intermediate materials: that are subject to restrictions in Annex II, or: for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material, and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant. – *Please contact Kullaplast AB to receive this information.*
- (7) Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food. – *Please contact Kullaplast AB to receive this information.*
- (8) Specifications on the use of the material or article, such as: (i) type or types of food with which it is intended to be put in contact; (ii) time and temperature of treatment and storage in contact with the food; (iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information. – *Please refer to our Normpack Certificate which can be found at our website.*
- (9) When a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of Regulation (EU) No 10/2011. – *No functional barrier is used.*

## General Absence Declaration

We have received confirmation from our suppliers that their virgin materials are free from the substances mentioned below. In addition to this, these substances are not intentionally used in our production or added to our products by us. Consequently, we hereby declare that our products, made from virgin materials, does not contain the substances listed below.

However, this does not exclude the presence of negligibly slight traces (the absence has not been checked by tests) due to, amongst others, impurities in materials or components supplied by external parties.

- Adipates.
- Alkylphenol ethoxylates (APEO) and other alkylphenol derivatives (substances that release alkylphenols on degradation).
- Allergens, examples include, without excluding any substance or food type not mentioned here: Gluten, Crustaceans, Molluscs, Egg, Fish, Peanuts, Soy, Milk incl. lactose, Almonds, Hazelnut, Walnut Cashew, Pecan, Brazil nut, Pistachio, Macadamia nut, Lupine, Celery, Mustard, Sesame seeds Sulphur dioxide, Sulphite.
- Ammonia.
- Antimicrobial substances.
- Biocidal products.
- Bisphenols (all kinds, i.e., including but not limited to: A, B, F and S).
- Boric acid, sodium perborate, perboric acid, sodium borate (borax) and any other boron compounds classed as carcinogenic, mutagenic or reprotoxic.
- Bovine spongiform encephalopathy (BSE).
- Brominated flame retardants, examples include, without excluding any substance not mentioned here: Polybrominated biphenyls (PBB), Polybrominated diphenyl ether (PBDE).
- Cadmium (Cd).
- Carcinogenic substances.
- Cellulose.
- CFCs and HCFCs.
- Chlorinated hydrocarbons such as PVC, PE-C, PVdC, etc..
- Chromium, hexavalent (Cr<sup>6+</sup>).
- Conflict Minerals. We have received confirmation from our suppliers that for the vast majority of our raw materials the following minerals and their derivatives are either not used in the production of our raw materials, or complies with the applicable regulations: Columbite-Tantalite, also known as Coltan (niobium, tantalum); Cassiterite (tin), Wolframite (tungsten), Gold.
- Conservatives.
- Disinfection chemicals.
- Endocrine disruptors.
- Lead (Pb).
- Mercury (Hg).
- Mutagenic substances.

- Organic solvents e.g., dimethyl fumarate (DMF), ethyl acetate, ethanol, ethers, etc., including any solvent not mentioned here.
- Perfluorinated and polyfluorinated alkylated substances (PFAs) including perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).
- Persistent, bioaccumulative and toxic substances (PBT).
- Phthalates, examples include, without excluding any substance not mentioned here: butyl benzyl phthalate (BBP), di-n-butyl phthalate (DBP), diisobutyl phthalate (DIBP), di-(2-ethylhexyl) phthalate (DEHP).
- Polyvinylchloride (PVC).
- Polystyrene.
- Radioactive substances.
- SIN-list substances, please refer to paragraph below.
- Substances of Very High Concern (SVHC) included in the most recent and authentic "[Candidate List](#) of Substances of Very High Concern for Authorisation", in a concentration above the threshold limit of 0.1%.
- Substance included in the most recent version of REACH Annex XIV: List of substances subject to authorisation.
- Substance included in the most recent version of REACH Annex XVII: Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.
- Tin organic compounds.
- Toxic for reproduction.
- Transmissible spongiform encephalopathy (TSE).
- Very persistent and very bioaccumulative (vPvB).

### *The SIN List*

The [SIN \(Substitute it Now!\) List](#) is a globally used database of chemicals likely to be banned or restricted in a near future. The chemicals on the SIN List have been identified by [ChemSec](#) – the International Chemical Secretariat – as Substances of Very High Concern (SVHC) based on the criteria established by the EU chemicals regulation REACH. Thus, the SIN List is more comprehensive than the "Candidate List of SVHC for Authorisation", please refer to the paragraph regarding REACH above.

Unfortunately, several of our suppliers do not issue general statements regarding absence of chemicals included in the SIN List valid for their products (since this list is not a legal requirement), nor do they reveal the exact composition of their products. Consequently, Kullaplast does not have the information and knowledge to issue a statement regarding the absence of all chemicals included in the SIN List valid for all our products.

However, only a limited number of substances on the SIN-list can be expected to be used in the production of plastic packaging material, please refer to this KRAV self-declaration. Regarding polyethylene (PE) this number is further reduced when comparing the chemical structures of the substances with that of PE, leaving only two (2) possible substances to consider. Concerning these two substances (1,3-butadiene, CAS number 106-99-0, and

isoprene, CAS number 78-79-5) we have received written confirmation from our suppliers that they are not intentionally added to any of our raw materials.

To conclude, Kullaplast can, with a high degree of probability, assume that no substances on the SIN-list are present in our products.

### *Non-Intentionally Added Substances (NIAS)*

*Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food* defines Non-Intentionally Added Substances (NIAS) as “an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product”. Thus, it is impossible to truthfully declare the absence of NIAS in any plastic product within in the scope of Regulation 10/2011. This regulation also states that NIAS may be present in a plastic article without being included in the Union list. Nevertheless, a toxicological evaluation needs to be performed.

The major fractions of NIAS in Polyolefins are the oligomers, which are unavoidably formed during polymerisation and cannot be removed. A joint study of polyolefin producers demonstrated that oligomers migrating from all types of polyolefins only consist of linear and branched alkanes (POSH) and alkenes (POMH), no cyclic or aromatic compounds were found. The toxicological assessment of such migrants concluded that they are sufficiently characterised by the existing overall migration limit.

Another major group of NIAS in polyolefins are reaction- and decomposition products from antioxidants, many of them known as “Arvin-substances”. Another joint industry study confirmed that none of these Arvin-substances are genotoxic and that they can therefore be rated at least as “Cramer-class III”, allowing a daily consumption of 90 µg/person/day.

However, the NIAS-assessment must focus on the finished food contact article and consider the fact that the formation of NIAS is also influenced by thermal and mechanical treatment during conversion, as well as the mixture with other raw materials. Kullaplast AB use raw materials from renowned major multi-national material producers. Our conversion processes are run within the parameters these producers state for their materials. Our finished food contact articles have been subjected to, and passed, the migration tests stipulated in Commission Regulation (EU) No 10/2011.

Taking all the above into account, we reach the conclusion that the presence of NIAS in our products is such that it will not harm the final consumer of the foodstuff.

## Flexible sheets for waterproofing

### *Premium quality guaranteed - Internal revision according to IQD128*

The Swedish quality control mark “P-mark” have been discontinued by the responsible authority. The premium quality of our flexible sheets for waterproofing (Luft- och Ångspärr in Swedish) will be continuously guaranteed by our production management and control system, as defined in our Internal Quality Document (IQD) 128, appendix 1. This is verified by third party internal revision, currently conducted by [RISE Research Institutes of Sweden](#).

This means that the product does not only meet the regulatory requirements, but also the even more stringent market demands, e.g. tensile strength after ageing (which is not required by the “CE regulations”). Furthermore, the product is tested by an external laboratory, and our production control system is audited once a year.

### *Approved and certified for the Norwegian market - TG*

Our flexible sheets for waterproofing (150 & 200 µm thickness, “dampsperre” in Norwegian) are tested and approved by [SINTEF Certification](#) and we have received the certificate “Teknisk Godkjenning no. 20056”.



### *CE marking*

Our flexible sheets for waterproofing are tested by *RISE Research Institutes of Sweden* (Notified Body, no 0402) according to the harmonised standard *EN 13984:2013 Flexible sheets for waterproofing. Plastic and rubber vapour control layers. Definitions and characteristics*. Thus, these products fulfil the requirements of *Regulation (EU) No 305/2011 Construction Products Regulation (CPR)* and bears the prescribed CE mark. Declarations of Performance are available on request.



### *Use in Nordic Swan Ecolabelled buildings (Svanenmärkta byggnader)*

Our flexible sheets for waterproofing (Kullafolie 120 & 200) are listed in the database for building products that can be used in Nordic Swan Ecolabelled buildings. Please refer to the [Nordic Swan Ecolabel](#) website for further details.

### *Assessment by/Registered at Byggvarubedömningen, BASTA and SundaHus*

Kullafolie 120 & 200 have also been registered and assessed by [Byggvarubedömningen](#) and [SundaHus](#).

Kullafolie 120 & 200 are registered at BASTA. This means that we can verify that our products meet the BASTA-criteria regarding properties hazardous to the environment and health. Please refer to [www.bastaonline.se](http://www.bastaonline.se).



**BYGGVARUBEDÖMNINGEN™**



## General Information

### *Tolerances*

STANDARD TOLERANCES, not applicable to Pallet Hoods

Thickness: average  $\pm 7\%$ , single value  $\pm 15\%$

Width, <1500 mm: + 10 mm, - 5 mm

Width, >1500 mm: + 20 mm, - 5 mm

Length (only bags, sacks, sheets): + 10 mm, - 5 mm

PALLET HOODS TOLERANCES

Thickness: average  $\pm 10\%$ , single value  $\pm 20\%$

Width: + 30 mm, - 15 mm

Length: + 10 mm, - 5 mm

CUSTOM TOLERANCES

Custom tolerances are used upon request and replace corresponding standard tolerances.

### *Marking*

Kullaplasts Product Identification for traceability, according to customer specification and, if applicable, to standards and regulations. Please let us know if you have any requests regarding marking.

### *Degradation, Storage, and Transportation*

Polyethylene degrades when exposed to UV radiation, heat or extensive mechanical wear. Thus, with regards to maintaining the mechanical properties of our products, storage must be done free from UV-radiation, should be done in a dry location, at a non-elevated temperature and in a closed outer packaging. Kullaplast recommends usage within two years and the use of approved EUR-pallets.

### *Melting point*

Polyethylene does not have a distinct melting point, instead there is an interval ranging from ca 115 °C to 140 °C depending on quality and density.

### *Ignition, fire and fire fighting*

Our products have no fire classification. However, ignition temperature for polyethylene is above 300 °C. On the other hand, once ignited, polyethylene could be difficult to extinguish. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment, e.g. water spray, powder, foam, carbon dioxide.

### *ISCC - certified renewable raw materials*



Kullaplast AB have an ISCC PLUS certification according to the standard *ISCC EU 203 Traceability and Chain of Custody*. This allows us to buy ISCC-certified renewable and recycled raw materials with the same high quality as virgin fossil raw materials, and to manufacture and sell ISCC-certified products.

Use of ISCC-certified raw materials are your choice, if you would like to promote this choice using e.g. ISCC logos and/or claims you will need an ISCC-certification or an ISCC-license. This will allow you different levels of use of ISCC logos and/or claims on your products, website, documentation, etc.. Please contact our Quality Manager, your sales contact or the [ISCC website](#) if you would like to have more information regarding these materials.

### *Recycling*

Most of our products are made almost exclusively from polyethylene (PE); however, in a few products there is some polypropylene (PP) or Ethyl Vinyl Acetate (EVA). Thus, all our products are suited to material recycling and should be recycled as polyethylene (PE) as this is the main component. Energy recovery is favourable since PE have a high energy density. Polyethylene is not hazardous waste. If you require specific information on your product, please contact our Quality Manager.



*Thank you for caring about our environment!*

### *Further or erroneous information*

If you require further information regarding any of the subjects above, or if any information is missing or appears erroneous, please contact our Quality Manager.

Most of the links to various websites in this document are updated outside of our control. Kullaplast AB does not take any responsibility regarding the availability of information or accessibility of websites if you chose to follow these links. Please refer to the main website of respective organisation if needed. We appreciate if you tell us about any broken link, thanks in advance.

### Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however, we do not assume any liability whatsoever for the accuracy and completeness of such information.

Thank you for your interest in Kullaplast AB and our products 😊

Höganäs, Sweden, 2022-04-14

Declarations, statements, and information above is hereby verified:



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Jonas Skoglund, CEO