



NORMPACK-CERTIFICATE

Registration No.: 134 15 001 2906 26

Valid until: 2012-01-19

We declare that our material/article is manufactured in accordance with the Normpack Norm.

Trade name (and type): AddiFlex HEV-HD

Material (material combinations): (Layer by layer, starting from the outside and inwards to the layer closest to the food):

Polyolefin + 7 % AddiFlex HEV-HD

Field of application: filling/storing (time/temperature): h/ °C; h/ °C; h/ °C

Suitable for food type(s) (according to 85/572/EG + 2007/19/EG):

Dry , Aqueous , Acid , Alcoholic , Fatty

Ref.no: 01 , 02 , 03 , 04 , 05 , 06 , 07 , 08

Not suitable for ref.no: 01.01 , 01.02 , 01.03 , 02.05.A , 02.06.A , 03.01 , 03.02.A.I , 03.02.B.I , 04.02.C.II , 04.03 A,B , 04.05.C.II , 05.01 , 05.02 , 06.01 , 06.03 , 06.04 , 06.05.B , 07.01 , 07.02 , 07.03 , 07.04 , 08.02 , 08.03.A.I,B.I , 08.06.B , 08.06.C , 08.07 , 08.08.I , 08.10.I , 08.13

Other information: Migration test has been done with films made with AddiFlex HES

Regulations: LIV FS 2003:2 with any subsequent reprints and amendments, the Normpack Norm (see overleaf).

Overall migration (mg/dm²) or (mg/kg): mg/dm² or mg/kg

To food simulant: water , 3% acetic acid , 10% ethanol , olive oil , Isooctane , 50% ethanol , 95% ethanol

Time(s) and temperature(s) for migration tests: h/ °C; h/ °C; days/ °C

Specific migration – SML: 30 mg/kg, 0.6 mg/

CAS-no. or PM/ref-no.: 7617-31-4, 10476-84-3

Specify any (food) additive(s) (E-no./Multifunctional) if contents higher than 5 %:

Does the material/product have a functional barrier? Yes No

What is the ratio of food contact surface area to volume?: The ratio of food contact surface area to volume is not specified. It will vary according to the application. (Used to establish the compliance of the material or article, 2007/19/EG with any subsequent updates)

See further §3 of the Normpack Norm.

Has the company implemented a traceability system for materials/products in accordance with Art. 17, L 1935/2004
Yes No

Does the company have a working GMP system in accordance with L 2023/2006?
Yes No

If our product is further processed, the manufacturer/processor of the finished product is responsible that the migration demands are met. We also declare that should we on any occasion change the composition of our products in a way that would interfere with the declaration, we will inform your company.

The certificate is valid provided that the demands of §3 of the Normpack-Norm (see overleaf) are fulfilled.

Add-X Biotech AB

Company
2009-10-07

Date

Signature of product/production responsible

Anders Lundberg

Clarification of signature

The certificate documentation is audited by the Normpack secretariat.

2010-01-19

Date

Normpack stamp and signature

Kristina Salonen

Clarification of signature

SWEDISH MATERIAL NORM FOR MATERIALS AND ARTICLES IN CONTACT WITH FOODSTUFFS (The Norm) Updated June 2009

§1 Materials and articles in contact with foodstuffs shall meet the demands laid down in the Swedish Food Act (SFS2006:804) and the European Directive no. 178/2002/EC, the Food Decree (SFS 2006:813), the Directives nos. 2232/96/EC and 1935/2004/EC, the Ordinance for materials and articles intended to come into contact with foodstuffs (LIVSFS 2003:2, updated by LIVSFS 2006:20), the Ordinance on nutritional supplements (LIVSFS 2003:9), on food additives (LIVSFS 2003:9, updated by LIVSFS 2003:20), on Foreign Substances in Food (SLV FS 1993:36 with amendments). **With any subsequent reprints and amendments.**

The following Decrees and Recommendations in force, specific for materials and products for food contact, are included in the Normpack-Norm:

EU-Ordinances 2232/96, 178/2002 (the Food Act), 1935/2004 (the Frame Regulation), 1895/2005 (Epoxy derivatives), 2023/2006 (GMP), 372/2007, 597/2008 (Plasticizers in lid gaskets), 282/2008 (Recycled Plastic) and the EU-Directives 78/142 (VCM), 80/766, 81/432, 86/572 (Food simulants), 82/711 (Test conditions, amended by 97/48), 2004/1 (Azo), 2004/24 (Cellophane), 2005/31 (Ceramic), 2007/142, 2002/72, 2008/39 (Plastic), 2004/19, 2005/79 and 2007/19, (Plastics and lid gaskets),

§2 For materials not covered in detail in Swedish food legislation one of the following regulations shall be invoked:

- The Dutch Packaging and Food-Utensils Regulation (Warenwet), Holland
- Kunststoffe im Lebensmittelverkehr, Empfehlungen des Bundesinstitutes für Risikobewertung (BfR), and Bedarfsgegenständeverordnung published in Bundesgesundheitsblatt, Germany
- Code of Federal Regulations, 21, Food and Drugs, §§ 174, 175, 176, 177, 178, 180, 181, 182, 184, 186 and 189, (FDA), USA

§3 To prevent incorrect usage of materials and articles in contact with foodstuffs, supplier and buyer at all manufacturing and handling levels shall confer about the suitability of the product for the intended purpose.

§4 Temporary Norm for Cellulose Based Materials (Except Cellophane) in Contact with Foodstuffs

4.1 Fibrous raw materials may be used for materials in contact with fruit and vegetables that are usually washed and/or peeled provided that the material meets the general purity demands according to BfR, Empf. XXXVI.

4.2 Fibrous raw materials may be used for materials in contact with dry food products provided that the material meets the general purity demands according to BfR, Empf. XXXVI. Only such recycled fibres may be used that are defined in BfR, Empf. XXXVI A.1.4 and with special consideration to footnotes 2 and 2a. "Untersuchungen von Papieren, Kartons und Pappen für den Lebensmittelkontakt, Wiedergewinnung von Papierfasern", section 2, "Begriffe".

4.3 Fat or wet foodstuffs should not be in direct contact with materials containing recycled fibres. If the material contains recycled fibres, there should be a functional barrier between the foodstuff and the material. (Recommendation from the Swedish Food Administration).

4.4 As the BfR Empf. XXXVI does not refer to materials with barrier layers, the migration of foreign substances is not allowed to exceed 10 mg/dm² according to the Warenwet legislation, Chapter II.

4.5 BfR Empf. XXXVII, XXXVII/2 and XXXVI/3 shall be followed without remarks according to the BfR recommendations.

4.6 The material shall always maintain a high microbiological purity adapted to the foodstuff in which it will come into contact.

§5 Temporary Norm with amendments for additives with limits in plastic materials: (EU) Directives 02/72, 04/19, 05/79, 07/19, 08/39, EU ordinances 2023/2006, 372/2007 and 597/2008.

If there is a limit regulating materials and articles, the following alternative methods are suggested to establish whether the product meets the demands of 02/72/EEC with subsequent amendments:

1. Measurements using standardised methods
2. Measurements using fully validated or recommended methods
3. Mathematical calculations
4. If methods 1, 2 and 3 are not available, a method of measurement working satisfactorily with reference to the fixed limit value can be used until a fully validated method of measurement has been established.

§6 Temporary Norm for printing inks. Description of legal status of printing inks in contact with foods.

Important www-addresses: http://www.innventia.se/templates/STFIPage_7100.aspx

<http://www.slv.se>,

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

<http://bfr.zadi.de/kse/faces/DBEmpfehlung.jsp?lang=en>

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

<http://warenwet.sdu.nl/warenwetonline/warenwet.exe?location=none&language=nl>