

Declaration of conformity

For materials intended to come into contact with food

Holeki NV
Vantegemstraat 12
B-92 30 WETTEREN
Belgium

NIJVERDAL, 09-01-2023

Article reference : 20293

HDPE | EasyOpen zakken 650/225 x 620 x 0.012 mm | Blue 1%

We declare that the above -mentioned product (s) produced by *Sylvaphane Plastics B.V., Feithsweg 14, 9356 AS Tolbert, The Netherlands* supplied by *Niverplast B.V., Baruch Spinozastraat 2, 7442 PD NIJVERDAL, The Netherlands* is in compliance with :

1. Issued by

Niverplast (Hereinafter referred to as "We", "Us", or "Our").

2. Manufactured/imported by

Identical to the details listed under point 1 within this document .

3. Identity of the product

Delivered HDPE Easy Openbags several dimensions , thickness and colours (Hereinafter referred to as "Product").

Product type: final product

Product description : HDPE Easy Open bag

Compliance work based on : HDPE folie 68 micron 223639

4. Issue date 15-04-2022

5. Applicable legislation and purity confirmation

European Commission Regulation definition:

- 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 and repealing Directives 80/590/EEC and 89/109/EEC, (hereinafter referred to as "Regulation (EC) No 1935/2004").
- 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 , amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food , amended up to Commission Regulation (EU) 2020/1245 of September 2020, (hereinafter referred to as "Regulation (EU) No 10/2011").
- 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, amended up to

COMMISSION REGULATION (EU) 2015/1906 of 22 October 2015, (hereinafter referred to as "Regulation (EC) No 282/2008").

A. Europe

i. Compliance with the requirements of the Framework Regulation

- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General safety aspects : YES
- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

ii. Compliance with the requirements of the Plastics Regulation

- Regulation (EU) No 10/2011: YES
- Plastics used to produce this Product and not separated from the food by a functional barrier are manufactured from only monomers , other starting substances and additives authorized under Regulation (EU) No 10/2011.

iii. Compliance with the requirements of the Recycled Plastics Regulation

- Regulation (EC) 282/2008: NOT APPLICABLE

iv. Other EU legislation

- Other EU legislation : NOT SPECIFIED

B. Member State legislation and non-European legislation

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non -plastic materials , are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below .

National legislation in EU Member States

Material group	Country	Legislation
COLOURANTS & PIGMENTS Status: Complaint	Netherlands - Hoofdstuk XI - Kleurstoffen en pigmenten	Regeling van de Minister van Volksgezondheid , Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen), geamendeerd tot aan Regeling 1028394-156011-VGP van de Minister van Volksgezondheid , Welzijn en Sport van 26 oktober 2016. Hoofdstuk XI -Kleurstoffen en pigmenten <u>Specifications of use</u> n/a

PLASTICS Status: Complaint	Netherlands - Hoofdstuk I - Kunststoffen	Regeling van de Minister van Volksgezondheid , Welzijn van 14 maart 2014, kenmerk 328583- 117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen), geamendeerd tot aan Regeling 1028394-156011-VGP van de Minister van Volksgezondheid, Welzijn en Sport van 26 oktober 2016. Chapter I - Plastics <u>Specifications of use</u> n/a
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Legislation for countries outside the EU

Material group	Country	Legislation
COLOURANTS & PIGMENTS Status: Complaint	United States § 178.3297	U.S. Food and Drug Administration CFR - Code of Federal Regulations Title 21 § 178.3297- Colorants for polymers <u>Specifications of use</u> n/a
GENERAL Status: Complaint	United States - 21 CFR 174.5 General requirements	General requirements <u>Specifications of use</u> n/a
PLASTICS Status: Complaint	United States - § 177.1520	TITLE 21--FOOD AND DRUGS CHAPTER I-- FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER B-- FOOD FOR HUMAN CONSUMPTION (CONTINUED) PART 177 INDIRECT FOOD ADDITIVES : POLYMERS B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces § 177.1520 - Olefin polymers. <u>Specifications of use</u> n/a

C. Non-intentionally added substances

Non-intentionally added substances in plastics , according to Article 6(4a) of Regulation (EU) No 10/2011, and in non- plastic materials , are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004. Adequate information on non -intentionally added substances can be found in section 6A of this document.

D. Overall migration limit

This product complies with the overall migration limit tested under the following conditions :

Simulants			
- A - Ethanol 10% (v/v) : < 1,0 mg/dm ²			
- B - Acetic acid 3% (w/v) : < 1,0 mg/dm ²			
- D2 (assigned fatty food simulant)- Vegetable oil . This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011. : 8,0 mg/dm ²			
Test conditions			
Test number	Test conditions	Intended food contact conditions	Covers also food contact conditions described for
OM2	10 d at 40 °C	Any long term storage at room temperature or below , including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t =	Test OM2 covers also food contact conditions described for OM1 and OM3.

E. Organoleptic properties

We have not determined whether a material or final article that is produced with this Product will induce an unacceptable change in the composition of the food or will cause deterioration of the organoleptic properties of the food. It is the responsibility of the downstream user to perform these tests .

6. Limits, restrictions and compositional specifications

A. Limits and restrictions of non-listed substances

Europe - Framework Regulation (EC) No 1935/2004 GENERAL		
Methyl 3-(3,5-ditert-butyl-4-hydroxyphenyl)propionate	CAS number: 6386-38-5 Reference number:-	Fat-reduction factor : unknown
Maximum concentration:-	Maximum Use Level:-	

Restrictions and specifications SML:

(1) 0,96 mg/kg

SML(T) Remark:

(1) TDI= 0,016 mg/kg bw/day

Netherlands - Hoofdstuk XI - Kleurstoffen en pigmenten COLOURANTS & PIGMENTS

Zinc

CAS number: 0007440-66-6

Fat-reduction factor:-

Reference number:-

Maximum concentration:-

Maximum Use Level:-

Restrictions and specifications SML:

(1) 25 mg/kg

SML(T) Remark:

(1) The specific migration of ingredients of colourants and pigments, under reasonably expected conditions of use, multiplied by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be exceeded.

Netherlands - Hoofdstuk XI - Kleurstoffen en pigmenten COLOURANTS & PIGMENTS

Copper

CAS number: 0007440-50-8

Fat-reduction factor:-

Reference number:-

Maximum concentration:-

Maximum Use Level:-

Restrictions and specifications SML:

(1) 5 mg/kg

SML(T) Remark:

(1) The specific migration of ingredients of colourants and pigments, under reasonably expected conditions of use, multiplied by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be exceeded.

B. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

FCM number	EEC reference number	CAS number	Substance name	Maximum concentration	Maximum use level
264	22660	0000111-66-0	1-octene	-	-
356	18820	0000592-41-6	1-hexene	-	-
433	68320	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	-	-
500	38560	0007128-64-5	2,5-bis(5-tert-butyl-2benzoxazolyl)thiophene	-	-
715	46880	0065140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	-	-

C. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

i. Restrictions: Annex I - table 1

FCM number	Fat-reduction	Restriction(s)	Restrictions and specifications factor	Notes
264	no	SML: (1) 15 mg/kg	-	-
356	no	SML: (1) 3 mg/kg	-	-
433	yes	SML: (1) 6 mg/kg	-	-
500	yes	SML: (1) 0,6 mg/kg	-	-
715	no	SML: (1) 6 mg/kg	-	-

ii. Group restrictions: Annex I - table 2

No group restrictions are present .

iii. Notes on verification of compliance: Annex I - table 3

No notes on verification of compliance are present .

D. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals

Name / Element	Restriction	Maximum concentration
Aluminium (Al)	SML:(1) 1 mg/kg	-
Copper (Cu)	SML:(1) 5 mg/kg	-
Zinc (Zn)	SML:(1) 5 mg/kg	-

E. Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines

This Product may contain Primary Aromatic Amines according to Annex II : NO

F. Compliance confirmation

This Product complies with the limits and restrictions in points 6A, 6C, 6D and 6E within this document , based on worst-case calculations , migration modeling or migration testing .

Specific migration is tested under the following conditions :

Test conditions			
Contact time :	Above 6 months at room temperature and below .	Contact temperature :	10 days at 60 °C
Test time :	10 days	Test temperature :	60 °C

The following substances with limitations in this Product have not yet been risk assessed by Us and therefore need to be evaluated by the downstream user based on the information listed below :

i. Substances listed in Regulation (EU) No 10/2011, Annex I

- All substances comply with the applicable limitations .

ii. Substances listed in Regulation (EU) No 10/2011, Annex II, Metals

- All metals comply with the applicable limitations .

iii. Substances listed in Regulation (EU) No 10/2011, Annex II, Primary Aromatic Amines

- Primary Aromatic Amines will not migrate in detectable quantities above the applicable detection limit .

G. Inks, coatings or adhesives

In case this Product is printed on , covered by a coating , or if different layers are held together by adhesives , We confirm that substances listed in Annex I , coming from inks, adhesives or coatings used in this Product , comply with the relevant restrictions .

This Product may contain substances with limitations listed in the tables under 6A or 6B within this document coming from inks , adhesives or coatings but may not be identified as such by Our suppliers .

7. Dual Use Additive(s)

A substance is defined as a "Dual Use Additive " if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring , regardless of its purity or whether or not the substance is subject to a restriction in food and /or in the plastic . In the case of salts it is the salt that matters , not the authorized acid , phenol or alcohol .

Number (E or FL)	Name	Maximum concentration
E 170	Calcium carbonate	-
E 172	Iron oxides and hydroxides	-
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)	-
E 171	Titanium dioxide	-
E 173	Aluminium	-
FL 1.070	1-Octene	-
FL 8.015	Octadecanoic acid	-

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

8. Specifications for use

Specifications of use as regards of type or types of food

All types of food : aqueous acidic and alcoholic foods (up to 10% alcohol) and foods that containing fats and oils .

Specifications for use as regards of time and temperature of treatment and storage of food

Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below , including hotfill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = $120/2^{((T-70)/10)}$ minutes.

Any other limitations of use

Compliant with the provisions within Regulation (EU) No 10/2011 for infants and young children : Not tested.

Compliant with the provisions within Regulation (EU) No 10/2011 for repeated-use articles: Not tested.

A surface/volume ratio expressed in dm² FCM/kg food of: 6 dm² FCM/ kg food.

9. Functional barrier

This Product contains a functional barrier : NO

Legend

If the compliance assessment is based on a worst -case family strategy , the identity of the product on which the compliance assessment is based will be indicated here .

* Substances marked with a single asterisk in this document are reportable substances with variable concentrations due to variations in supply source .

** Substances marked with a double asterisk in this document are not present in this Product .
However, they are included in this document due to compliance assessment of a worst -case product.

*** Substances marked with a triple asterisk in this document are substances to which both remarks * and ** apply.
For all substances with a single asterisk , *, you are advised to contact your supplier before carrying out any specific migration tests to verify the concentration of the substance within this Product .

EXCP¹: If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination , 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 .

EXCP²: If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination , 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 .

Best regards,

Rachel Hofman
Niverplast B.V.

Disclaimer

The information included in this document is based on the present state of our knowledge and is valid from the stated issue date until this document is superseded . Because of possible changes in the underlying legislation and regulations, as well as possible changes in this Product , we cannot guarantee that the status of this document will remain unchanged . It will be renewed in all cases where the previous conformity is no longer ensured .