

Analytical report AR-17-JR-011794-02

This report replaces report number: AR-17-JR-011794-01



Sample Code 799-2017-00106836

Reference	Bomba manual polietilena pequena TP-056 Proquifarma S.L. Carrer de Sostres, 17 Local 1 08024, Barcelona
Client sample code	17002870
Purchase order code	00878/17
Number of received Samples	1
Ordered by	Mrs. Sara Caparrós Díaz
Submitted by	Mrs. Nuria Fernandez
Carrier	Other
Reception date	26.05.2017
Packaging	plastic bag
Start/end of analyses	29.05.2017 / 16.06.2017

TEST RESULTS

Physical-chemical Analysis

JJ0HQ Overall migration in 3% acetic acid (#)

Method: EN 1186, , Gravimetry

Migration Type	Immersion	
according to EN	1186-3	
Temperature	40	°C
Duration of experiment	10	days
Replicate 1	<2	* mg/dm ²
Replicate 2	<2	* mg/dm ²
Replicate 3	<2	* mg/dm ²
Mean	<2	* mg/dm ²
surface volume ratio	1/100	dm ² /ml
Layer thickness	>= 0.5 mm	
Variation from Norm	No	

The results of examination refer exclusively to the checked samples.

Duplicates - even in parts - must be authorized by the test laboratory in written form.

Eurofins CPT GmbH · Am Neuländer Gewerbepark 4 · D-21079 Hamburg

Place of execution and place of jurisdiction is Hamburg Registered Office: Hamburg - lower district court Hamburg HRB 103427 Commercial

Register: Amtsgericht Hamburg HRB 103427

General Manager: Thomas Herrmann (Dipl.-Ing.)

Our General Terms & Conditions of Sales are applicable - All contracts will be carried out in accordance with our General Terms and Conditions (GTC).

VAT No.: DE 258 239 846

BLZ: 250 500 00, Kto.-Nr.: 199 917 246

IBAN: DE 67 2505 0000 0199 9172 46

SWIFT: NOLA DE 2HXXX

Ust ID Nr: DE 258 239 846

Our General Terms & Conditions, available upon request and online at
<http://www.eurofins.de/lebensmittel/kontakt/avb.aspx>, shall apply.



Durch die Deutsche Akkreditierungsstelle GmbH
akkreditiertes Prüflaboratorium

DIN EN ISO/IEC 17025:2005

Die Akkreditierung gilt für die in der Urkunde
aufgeführten Prüfverfahren

This report replaces report number: AR-17-JR-011794-01

JJ0TZ Overall migration in 10% ethanol (#)

Method: EN 1186, , Gravimetry

Migration Type	Immersion	
according to EN	1186-3	
Temperature	40	°C
Duration of experiment	10	days
Replicate 1	<2	* mg/dm ²
Replicate 2	<2	* mg/dm ²
Replicate 3	<2	* mg/dm ²
Mean	<2	* mg/dm ²
surface volume ratio	1/100	dm ² /ml
Layer thickness	>= 0.5 mm	
Variation from Norm	No	

JR0BP Overall migration in 20% ethanol (#)

Method: EN 1186, , Gravimetry

Migration Type	Immersion	
according to EN	1186-3	
Temperature	40	°C
Duration of experiment	10	days
Replicate 1	<2	* mg/dm ²
Replicate 2	<2	* mg/dm ²
Replicate 3	<2	* mg/dm ²
Mean	<2	* mg/dm ²
surface volume ratio	1/100	dm ² /ml
Layer thickness	>= 0.5 mm	
Variation from Norm	No	

The results of examination refer exclusively to the checked samples.

Duplicates - even in parts - must be authorized by the test laboratory in written form.

Eurofins CPT GmbH - Am Neuländer Gewerbepark 4 - D-21079 Hamburg

Place of execution and place of jurisdiction is Hamburg Registered Office: Hamburg - lower district court Hamburg HRB 103427 Commercial

Register: Amtsgericht Hamburg HRB 103427

General Manager: Thomas Herrmann (Dipl.-Ing.)

Our General Terms & Conditions of Sales are applicable - All contracts will be carried out in accordance with our General Terms and Conditions (GTC).

VAT No.: DE 258 239 846

BLZ: 250 500 00, Kto.-Nr.: 199 917 246

IBAN: DE 67 2505 0000 0199 9172 46

SWIFT: NOLA DE 2HXXX

Ust ID Nr: DE 258 239 846

Our General Terms & Conditions, available upon request and online at

<http://www.eurofins.de/lebensmittel/kontakt/avb.aspx>, shall apply.Durch die Deutsche Akkreditierungsstelle GmbH
akkreditiertes Prüflaboratorium

DIN EN ISO/IEC 17025:2005

Die Akkreditierung gilt für die in der Urkunde
aufgeführten Prüfverfahren

This report replaces report number: AR-17-JR-011794-01

* = Below indicated quantification level

(#) = Eurofins Consumer Product Testing (Hamburg) is accredited for this test.

JUDGEMENT

According to §31 of the German Food and Feed Code (Lebensmittel- und Futtermittelgesetz, LFGB) and the European Framework-Regulation VO (EC) No. 1935/2004 food contact materials may not release substances in food or its surface in quantities that could

1. endanger human health
2. bring about an unacceptable deterioration of the composition or the organoleptic properties (smell, taste) or the appearance of food (e.g. colour)

The overall migration from plastic articles in contact with food may not exceed 10 mg/dm² packaging material, according to the European Plastics-Regulation VO (EC) No. 10/2011.

- Simulant A - below limit value
- Simulant B - below limit value
- Simulant C - below limit value

In the scope of the analyses performed and under the above test conditions there was no indication for an objection.

Signature 
 Analytical Service Manager (Jana Wissel)

The results of examination refer exclusively to the checked samples.

Duplicates - even in parts - must be authorized by the test laboratory in written form.

Eurofins CPT GmbH - Am Neuländer Gewerbepark 4 - D-21079 Hamburg

Place of execution and place of jurisdiction is Hamburg Registered Office: Hamburg - lower district court Hamburg HRB 103427 Commercial

Register: Amtsgericht Hamburg HRB 103427

General Manager: Thomas Herrmann (Dipl.-Ing.)

Our General Terms & Conditions of Sales are applicable - All contracts will be carried out in accordance with our General Terms and Conditions (GTC).

VAT No.: DE 258 239 846

BLZ: 250 500 00, Kto.-Nr.: 199 917 246

IBAN: DE 67 2505 0000 0199 9172 46

SWIFT: NOLA DE 2HXXX

Ust ID Nr: DE 258 239 846

Our General Terms & Conditions, available upon request and online at
<http://www.eurofins.de/lebensmittel/kontakt/avb.aspx>, shall apply.



Durch die Deutsche Akkreditierungsstelle GmbH
 akkreditiertes Prüflaboratorium

DIN EN ISO/IEC 17025:2005

Die Akkreditierung gilt für die in der Urkunde
 aufgeführten Prüfverfahren

Bildanhang zu Prüfbericht: AR-17-JR-011794-02
Proben-Nummer: 799-2017-00106836

Bomba manual polietilena pequena TP-056



Analytical report AR-19-JR-001856-02

This report replaces report number: AR-19-JR-001856-01



Sample Code 799-2018-00156215

Reference	Bomba Manual PolietilenoPequena TP-056 PROQUIFERMA S.L. Carrer de Sostres, 17 LOCAL 1 08024 BARCELONA
Client sample code	18008634
Purchase order code	01819/18
Lot-no.	N/A
Number of received Samples	1
Ordered by	Prüfbericht
Submitted by	Mr. Antoni Mas
Carrier	GLS
Reception date	21.12.2018
Start/end of analyses	28.12.2018 / 23.01.2019

TEST RESULTS

Physical-chemical Analysis

JR0EM Screening from food simulant 95%Ethanol (#)

Method: Internal, PV 01437 2018-09, GC-MS

Migration Type	Immersion	
Temperature	40	°C
Duration of experiment	10	days
surface volume ratio	1.2/100	dm ² /ml
Result	See Attachment	
Layer thickness	>= 0.5 mm	

(#) = Eurofins Consumer Product Testing (Hamburg) is accredited for this test.

JUDGEMENT

According to §31 of the German Food and Feed Code (Lebensmittel- und Futtermittelgesetz, LFGB) and the European Framework-Regulation VO (EC) No. 1935/2004 food contact materials may not release substances in food or its surface in quantities that could

1. endanger human health
2. bring about an unacceptable deterioration of the composition or the organoleptic properties (smell, taste) or the appearance of food (e.g. colour)

The results of examination refer exclusively to the checked samples.

Duplicates - even in parts - must be authorized by the test laboratory in written form.

Eurofins CPT GmbH · Am Neuländer Gewerbepark 4 · D-21079 Hamburg

Place of execution and place of jurisdiction is Hamburg Registered Office: Hamburg - lower district court Hamburg HRB 103427 Commercial

Register: Amtsgericht Hamburg HRB 103427

General Manager: Thomas Herrmann (Dipl.-Ing.)

Our General Terms & Conditions of Sales are applicable - All contracts will be carried out in accordance with our General Terms and

Conditions (GTC).

VAT No.: DE 258 239 846

Bank Name: UniCredit Bank AG

BLZ: 207 300 17, Kto.-Nr.: 7000 0016 50

IBAN: DE86 2073 0017 7000 0016 50

SWIFT: HYVEDEMM17

Our General Terms & Conditions, available upon request and online at

<http://www.eurofins.de/lebensmittel/kontakt/avb.aspx>, shall apply.



Durch die Deutsche Akkreditierungsstelle GmbH
akkreditiertes Prüflaboratorium

DIN EN ISO/IEC 17025:2005

Die Akkreditierung gilt für die in der Urkunde
aufgeführten Prüfverfahren

This report replaces report number: AR-19-JR-001856-01

During the manufacturing process reaction- and degradation-products of formulation components may be formed (so-called NIAS, non-intentionally added substances). If yes, the manufacturer has to prove their harmlessness according to internationally accepted scientific standards for risk-assessment. In the NIAS-screening substances were detected above the detection limit of 10 ppb (complete list see attachment)

Listed acc. Plastics-Regulation (EU) 10/2011, Annex I:

- Isopropyl myristate (FCM 878, SML = 60 mg/kg, scan #9)
- Stearamide (FCM 306, SML = 60 mg/kg, scan #16)
- Irganox 1076 (FCM 433, SML = 6 mg/kg, scan #20)

Plastic oligomers / POSH:

Some of the detected substances were technically not avoidable plastic oligomers (POSH, polyolefine saturated hydrocarbons), for which the authority labs so far do not issue complaints.

Not-listed substances / NIAS:

- CAS 124-19-6
- CAS 629-54-9
- CAS 124-19-6

For all these not-listed substances (NIAS) the manufacturer has to prove (according to internationally accepted scientific standards for risk-assessment) that Article 3 of the Framework-Regulation (EU) Nr. 1935/2004 is fulfilled, according to which food-contact-materials may not endanger human health. For this purpose, it should be checked whether the raw-material-suppliers might already have toxicological data in the form of TDI-values (tolerable daily intake) for them. If not, a risk-assessment needs to be performed.

Signature



Analytical Service Manager (Laura Tumm)

The results of examination refer exclusively to the checked samples.

Duplicates - even in parts - must be authorized by the test laboratory in written form.

Eurofins CPT GmbH - Am Neuländer Gewerbepark 4 - D-21079 Hamburg

Place of execution and place of jurisdiction is Hamburg Registered Office: Hamburg - lower district court Hamburg HRB 103427 Commercial

Register: Amtsgericht Hamburg HRB 103427

General Manager: Thomas Herrmann (Dipl.-Ing.)

Our General Terms & Conditions of Sales are applicable - All contracts will be carried out in accordance with our General Terms and Conditions (GTC).

VAT No.: DE 258 239 846

Bank Name: UniCredit Bank AG

BLZ: 207 300 17, Kto.-Nr.: 7000 0016 50

IBAN: DE86 2073 0017 7000 0016 50

SWIFT: HYVEDEMM17

Our General Terms & Conditions, available upon request and online at <http://www.eurofins.de/lebensmittel/kontakt/avb.aspx>, shall apply.



Durch die Deutsche Akkreditierungsstelle GmbH
akkreditiertes Prüflaboratorium

DIN EN ISO/IEC 17025:2005

Die Akkreditierung gilt für die in der Urkunde
aufgeführten Prüfverfahren

Sample number: 156215

Determination of organic compounds in Ethanol migrate (95 %)

Organic compounds of the Ethanol migrate (sample migrated in 100 mL Ethanol 95 %) were detected and quantified as equivalent of internal standards.

Migration conditions:

Time: 10 d

Temperature: 40 °C

Results:

Migration in mg/kg (real filled foodstuff- here Ethanol 95 %) as equivalent of internal standards:

Scan #	RT min.	MW	mg/kg*	Identification	CAS #
1	10.094			d-Phenol (IS 0-15 min)	
2	12.374	142	0,02	Nonanal	124-19-6
4	16.750	198	0,09	Tetradecane	629-59-4
5	19.216	226	0,32	Hexadecane	544-76-3
6	20.353	240	0,53	Heptadecane	629-78-7
7	21.111	N/MW	0,10	probably degradation product antioxidant	N/P
8	21.423	254	0,47	Octadecane	593-45-3
9	21.690	N/MW	0,21	Isopropyl myristate	110-27-0
10	22.158			d-Nonadecane (IS 15-25 min)	
11	22.567	N/MW	0,11	probably branched Alkylbenzene	N/P
12	22.700	N/MW	0,15	probably branched Alkylester	N/P
13	23.087	N/MW	0,18	probably Alkylphthalate	N/P
14	25.107	255	0,80	Palmitamide	629-54-9
15	26.756	N/MW	3,47	unsaturated Alkylamide	N/P
16	26.920	283	1,64	Stearamide	124-26-5
17	28.131			d-DEHP (IS 25-44 min)	
18	28.272	N/MW	0,10	unsaturated Alkylamide	N/P
19	28.450	N/MW	0,10	unsaturated Alkylamide	N/P
20	35.151	530	2,82	Irganox 1076	2082-79-3
21	37.246	N/MW	0,03	possibly aromatic compound	N/P
	sum	N/MW	18,38	Sum of branched hydrocarbons, Alkylaldehyde, Alkylalcohol and probably Mono-, Sesqui- and Triterpene derivatives	N/P
Sum			29,53		

Key: **N/MW** Not possible to determine molecular weight
 N/CAS No CAS Number Assigned to this compound
 N/P Not possible to assign a CAS Number because only functionality is named.

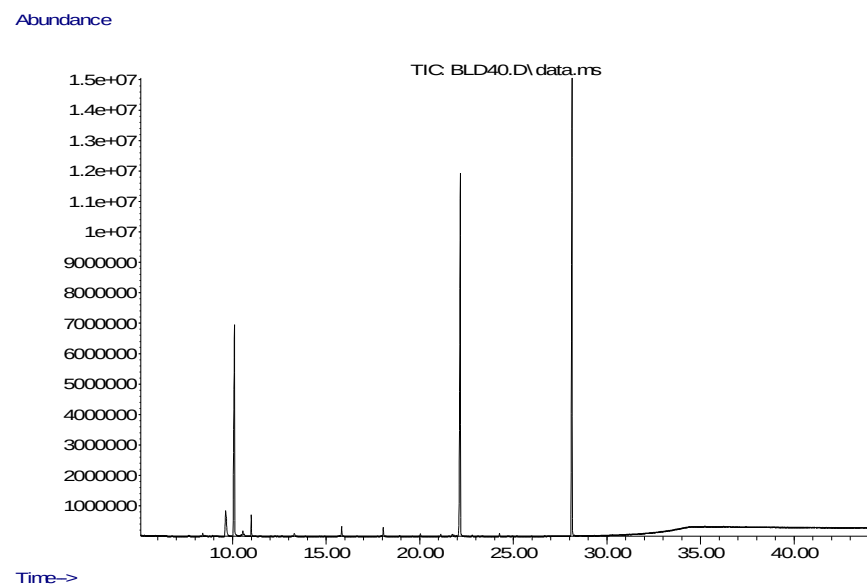
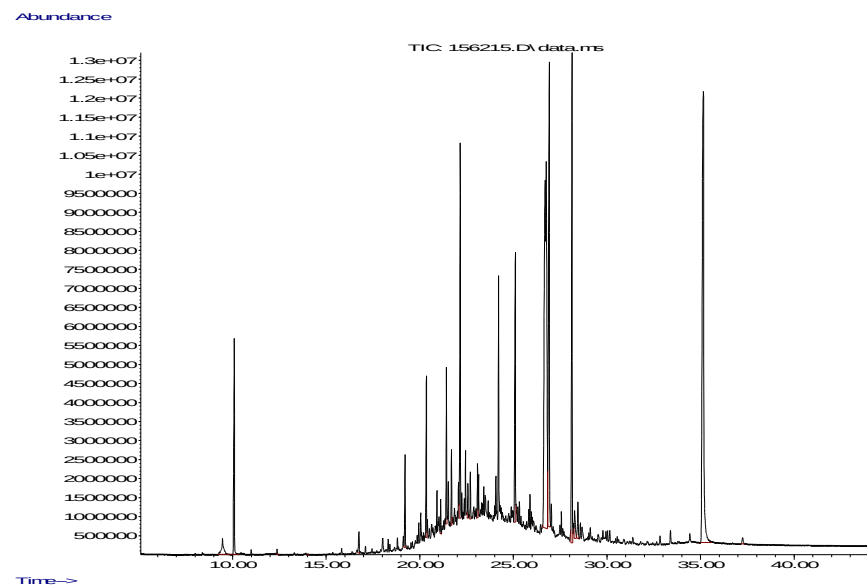
mg/kg*: for the EU-convention of 6 dm2 packaging for 1 kg food

Probably: 80 % fit with spectra library

Possibly: 60 % fit with spectra library

Analysis performed by: ATRAUTMANN/APANZER

Date: 23.01.2019



Not identified peaks: chromatography artefacts or peaks < 0.02 mg/kg*

PROQUIFERMA S.L.
Carrer de Sostres, 17 LOCAL 1
08024 BARCELONA

Hamburg, 31/01/19

Toxicological evaluation of migrated compounds

Eurofins CPT sample code 799-2018-00156215
Eurofins test report: AR-19-JR-001856-02
(Bomba Manual PolietilenoPequena TP-056)

The above sample material was analysed for NIAS („non-intentionally added substances“) with a GC/MS-screening following migration (10 days, 40 °C) into 95 % ethanol as food simulant. The test conditions were chosen according to the European Plastics-Regulation (EC) No. 10/2011 covering all storage times at refrigerated and frozen conditions including heating up to 70°C for up to 2 hours, or 100°C for up to 15 minutes, respectively. The following substances were identified and quantified in the screening:

Tab. 1: Substances identified in the NIAS-screening that are not listed in Annex I of the European Plastics-Regulation for which a risk-assessment is necessary using the TTC-model.

Substance / Trade Name	CAS-Nr.	Migration [mg/kg]	Cramer Class
Nonanal	124-19-6	0,02	*
Hexadecanamid	629-54-9	0,80	III

*: toxicological data available from the European Chemicals Agency (ECHA) webpage

In addition, several substances (such as Irganox 1076) approved in the Union-list were found in concentrations well below the respective limit values, if limited at all. Also, alkanes were detected which belong to the so-called POSH-fraction (polymeric saturated hydrocarbons).

POSH

POSH are linear and branched hydrocarbons which are generated during the polymerization of Polyethylene (PE) and Polypropylene (PP). In general, POSH consist of hydrocarbons with an evenly distributed number of carbon atoms and occur in plastics up to concentrations of several hundred ppm which may migrate into the packaged food depending on their chain length^{1,2,3}.

These POSH are not regulated in the European Plastics-Regulation (EC) No. 10/2011. The German BfR (Federal Institute for Risk-Assessment) suggested in Recommendation XXXVI for paper and board that hydrocarbons with a chain length of C₁₀-C₁₆ should not migrate in quantities higher than 12 mg/kg food⁴. The committee on toxicology of the German BfR further suggested an extension to hydrocarbons with a chain length of C₁₇-C₂₀ with a maximum tolerable migration of 4 mg/kg⁵.

Hydrocarbons with a more than 20 carbon atoms are accumulated in the liver and considered to be of higher toxicological relevance. Unfortunately there are no reliable toxicological data available until now so that a final judgment of such is not possible at the moment.

Method:**The TTC-model of the EFSA for a structure-based risk-assessment**

First the presence of structural alerts for genotoxicity is checked utilizing the Benigni-Bossa-model^{6,7}.

The EFSA (European Food Safety Authority) evaluated a model for the toxicological assessment of chemicals in 2012 in a statement⁸. Here, the so-called TTC-model („threshold of toxicological concern“) is recommended as a tool for the assessment of the human exposition with chemical substances for which the harmful effects are so low that now further toxicological data are necessary⁹. The EFSA classifies the following TDI-amounts (tolerable daily intake) as sufficiently conservative to be used as limits [$\mu\text{g}/\text{person}/\text{day}$]:

- 0.15: for substances with a structural feature for genotoxicity
- 18 : for organophosphates and carbamates with anti-cholinesterase-activity
- 90 : for substances of Cramer-classes II and III
- 1800 : for substances of Cramer-class I

For the classification of chemical substances into the so-called Cramer classes¹⁰ a complex decision-tree with 33 questions needs to be completed, which covers relevant chemical structural features as well as the natural occurrence in food and the human organism. According to this substances scheme the following three classes are defined:

- Class I: simple chemical structure, known metabolism pathways with harmless end products, therefore low oral toxicity
- Class II: structural characteristic(s) more dangerous than Class I but less dangerous than Class III, therefore toxic potential cannot be excluded
- Class III: structural characteristic(s) pointing to relevant toxicity, reactive functional groups, therefore considered unsafe

Result

Nonanal (CAS 124-19-6) was assessed by the European Chemical Agency (ECHA). A dossier for REACH registration is available on the ECHA website. According to these information the No observable adverse effect level of Nonanal is 20 000 mg/kg. Following the guideline for 'Risk Assessment of Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) under Article 19' of the European Plastics-Regulation (EU) No 10/2011 by PlasticsEurope a self-derived SML of 12 000 mg/person/day can be calculated using the above NOAEL.

For Hexadecanamid (CAS 629-54-9) the TTC-concept was applicable (no TTC-exclusion class). After completion of the decision tree it was classified as Cramer-class III. Consequently a maximum daily intake of 0.09 mg/Person can be considered as safe for consumers.

A consumption of 100 g of the food per day can, therefore, be judged as safe for human consumption, according to the TTC-concept evaluated and suggested by the EFSA.

Hamburg, 31/01/2019

Signature



Analytical Service Manager (Laura Tumm)

Literature

- ¹ Biedermann-Brem S, Kasprick N, Simat T, Grob K (2012) Food Add Cont 29(3), 449-60. Migration of polyolefin oligomeric saturated hydrocarbons (POSH) into food.
- ² Ausmaß der Migration unerwünschter Stoffe aus Verpackungsmaterialien aus Altpapier in Lebensmittel. Abschlussbericht zum Entscheidungshilfeprojekt des BMELV, Projektnummer 2809HS012 (<http://download.ble.de/09HS012.pdf>).
- ³ EFSA Scientific Committee (2012) EFSA J 10(7), 2750ff. Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC).
- ⁴ German Federal Institute on Risk Assessment (BfR): Recommendation XXXVI on paper and board for food contact, <http://kse.zadi.de>
- ⁵ Protocol of the 10th meeting of the BfR committee on commodities; <http://www.bfr.bund.de/cm/343/10-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf>
- ⁶ Benigni R, Bossa C, Jeliaskova N, Netzeva T, Worth A (2008). European Commission report EUR 23241 EN. The Benigni / Bossa rulebase for mutagenicity and carcinogenicity
- ⁷ Benigni R, Bossa C, Netzeva T, Rodomonte A, Tsakovska I (2007) Environ Mol Mutag 48, 754-71. Mechanistic QSAR of aromatic amines: new models for discriminating between mutagens and nonmutagens, and validation of models for carcinogens.
- ⁸ European Standards Agency (2013) ECHA-13-R-02-EN. Grouping of substances and read-across approach, <http://echa.europa.eu>
- ⁹ Dewhurst I, Renwick AG (2013), Regul Tox Pharm 65, 168-77. Evaluation of the Threshold of Toxicological Concern (TTC) – challenges and approaches.
- ¹⁰ Cramer GM, Ford RA, Hall RL (1978) Food Cosmet Toxicol 16, 255-76. Estimation of toxic hazard - a decision tree approach.