Product Specification and Certificate

Product no.	03829D-3000
Product name	Duma Twist-Off Cap 3829 D
Product description	45 mm round plastic child-resistant tamper-evident screw cap with three break-points on the tamper-evident ring and aperture for desiccant insert. Intended for the sealing of: - Duma Twist-Off 35 - 600 ml HDPE Containers - Duma Twist-Off Q 75 - 200 ml HDPE Containers
Design	• Regulatory drawing A03829D-3000 Regulatory • Standard drawing B03829D-3000
Raw material	Bormed HF840MO, Polypropylene (PP), Homopolymers in compliance with Regulation (EU) 10/2011, FDA title 21 CFR § 177.1520 'Olefin Polymers' and BfR recommendation VII 'Polypropylen', Borealis A/S. This product meets the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction - Identification, physicochemical tests (with exception of absorbance and total organic carbon tests), and extractable metals tests (as listed in the chapter). Plastic additive tests are done according to Borealis' internal methods. Coloured with 2.0 - 2.8% white masterbatch, containing approx. 59% titanium dioxide. HF840MO Declaration
Colour	PP 12455 White MB, Polypropylene (PP) in compliance with Commission Regulation (EU) No 10/2011, FDA title 21 CFR § 178.3297 and BfR recommendation IX, Avient (formerly Clariant). PP12455 Declaration
Production	**Facility:** Vaerloese, Denmark **Process:** The caps are injection moulded **Hygiene:** The production takes place in clean room **Sterilisation:** N/A

Measures and Properties

Dimensions:			
External:		Internal:	
Height	29.0 +0.5/-0.3 mm	Diameter	38.0 +0.3/-0.2 mm
Diameter	45.0 +0.5/-0.5 mm	Base ring	40.4 +0.2/-0.2 mm
		Sealing plug	31.9 +0.15/-0.15 mm
		Desiccant holder	18.9 +0.15/-0.15 mm
Other dimensions:			
Weight	10.6 +0.6/-0.6 g	Shelf life	5 years
Opening force	1.7 +0.5/-0.5 Nm	Bioburden	Max. 50 CFU
Complete with a load of approx.	80 N		

Application force	1.90 - 2.50 Nm

Test Results

The container and cap comply with all demands for Moisture Vapour Transmission and Light Transmission and are in accordance with USP <671>. Documentation enclosed.
MVT - 045256-3000/03829D-3000/MAR2017
LT - 03829D-3000/OCT2016

When applying the Twist-Off Cap to the corresponding container the package is Child-Resistant and suitable for senior adults.
Child-Resistant Statement 2829D & 3829D

The container and cap comply with all demands for Internal Reflectance and Differential Scanning Calorimetry and are in accordance with USP <661.1>. Documentation enclosed. Over time IR spectrum might show absorbance from release agent.
IR - HF840MO / PP12455
DSC PP/AUG2016

The container and cap comply with all demands for Physicochemical Tests set by the United States Pharmacopoeia USP 43 <661.2> Plastic Packaging Systems for Pharmaceutical Use and Biological Reactivity Tests, In vitro set by the USP chapter <87>. Documentation enclosed.
Physico - GF4760/HF840MO/Purell 2007H
In vitro - HF840MO/PP12455/JUN2016

Packing and Way of Delivery

The products are packed in 1 PE bag, which is then sealed. The PE bag is put into a cardboard carton, which is sealed with PP-tape. The cartons are packed on pallets, which are 1200 x 800 x 140 mm and weight approximately 23 kg.

Carton dimensions:
Height (mm): 340 Length (mm): 580 Width (mm): 385

Packing information:
Number of items per carton: 1100 Volume per carton (m³): 0.08
Max. number of cartons per pallet: 20 Weight per carton (kg.): 12.6
Max. height of the pallet (mm): 1900

Labelling

Each carton is provided with a label with the following information:
- Manufacturer name
- Material name and number
- Batch / lot number and quantity
- Customer information (if requested)
- Country of origin
- Shelf life
- Production date and machine number

Recommendation to Storage, Handling and Transportation & Information about Filling Line

Stored inside in clean conditions in its original un-open packaging, protected from direct sunlight and with a temperature between 5 - 35° C and Relative Humidity between 30 - 70 %.
Running-in of Duma Twist-Off Closure

Quality Control

All products are quality controlled according to instructions specified in our quality control system. We therefore guarantee that all deliveries from Primary Packaging Plastics have passed our control procedures and comply with the quality demands mentioned below. If required a certificate of conformance can be issued. The classification of defects and specifications of AQL values are based on ISO 2859 and Quality Assurance of Pharmaceutical and Cosmetic Packaging Materials:
Defect Evaluation List for Blow-moulded Plastic Containers Vol. 23 - ISBN 3-87193-405-6.
Defect Evaluation List for Injection-moulded parts made of Plastic: Closures, Sealing Disks and dosage aids (droppers, etc.) Vol. 22 - ISBN 3-87193-182-9.
Documentation enclosed.
Quality Control - Duma Twist-Off Cap with CR

Declaration of Conformity

DoC EP (HF 840MO)
DoC Food Law (HF840MO)
DoC TSE/BSE
Duma T-Off Cap&with Desic.& OneLiner&Pocket CR DoC Allerg, Phthal, BPA,Latex, Melam
DoC TBA_TCA

Information on Packaging and Packaging Waste Directive 94/62/EC and/or CONEG

Both container, cap and bag are produced from material, which complies with the directions for plastics material in contact with foodstuffs. The content of heavy metals in the products, the inner bag, and the carton is less than 100 ppm.
The products can be utilised by recovery of material and because of a high heating value by recovery of energy.

REACH

We can confirm that the raw materials used in the product are either pre-registered or exempted from pre-registration.

Complaint Handling

In case that the delivered products are outside specification, complaint must be send in writing to daily contact person in Customer Care Center.

In order to ensure a thorough investigation it is important to send the following basic information:

- Article number
- Batch number
- Cavity number (if related to specific cavities)
- Number of defective items
- Defect observed in
  - a) incoming control including sample size
  - b) production including quantity of items used
  - c) final products including quantity of items used
  - d) market complaint
- Defect found in
  - a) one carton
  - b) several cartons - please specify quantity

- Exact production date/time from carton/bag or carton/bag/pallet number products in quarantine:
  a) Filled products - Quantity
  b) Not filled products - Quantity
  c) No products left
- Description of the defect

The following standard form can be used: 3.1 Customer Complaint Report.

Depending on the defect, additional information will be requested as described in the attached standard forms: 2.5 Information requested in relation to complaints.

It is very important to send samples at the time a complaint is filed, as any delay in these can have an impact on time of investigation. An investigation report is send to Customer within 21 days counting from when complaint, relevant information and samples are received.

Important !
Filled or empty products involved in a complaint to Primary Packaging Plastics, must only be destroyed by Customer after written approval from Gerresheimer. Any activity in connection with a complaint where Customer expect Gerresheimer to cover the costs must be approved by Gerresheimer in writing before initiation of the activity.

Complaint report
Labelling
Loose silica gel-loose desiccant-defect on desiccant
Mix-up
Partly- or disconnected TE-rings
Product defect
Transport

Registrations and Certifications

Primary Packaging Plastics was established in 2020. Before that time the company was working under the following names: Gerresheimer Plastic Packaging, Superfos Pharma, Superfos Pharma Pack, Dudek Plast and Duma.
Documentation, i.e. test reports, certificates etc. issued before July 2020 will be with reference to one of the names above.

Gerresheimer Vaerloese A/S has obtained the following registrations and certifications for Vaerloese and Haarby, Denmark:
ISO 9001, no. 160454-2014-AQ-DEN-DANAK
ISO 14001, no. 156579-2014-AE-DEN-DANAK
ISO 15378, no. 160455-2014-Q-DEN-DNV
ISO 45001, no. 10000341648-MSC-DANAK-DNK

The product is FDA registered in US with the following DMF number:
DMF 12077 - DMF type III Packaging material, Manufactured in Vaerloese - Denmark, Haarby - Denmark.

The product is TPD registered in Canada with the following DMF number:

DMF 2000-108 - Packaging material – Drug Master File. Packaging material, Manufactured in Vaerloese - Denmark, Haarby - Denmark.

The product is registered in China with one of appropriate number:
B20190001892 – HDPE bottles. „I" inactive status.
B20190001894 – PP caps. „I" inactive status.
B20190001893 – LDPE caps. „I" inactive status.
B20200000747 – PP caps with Desiccant (includes Duma Desiccant Insert). „I" inactive status.

The product is registered in Russia with the following number:
C3 2011/11203 – plastic packages in size between 3ml to 3000 ml with accessories.

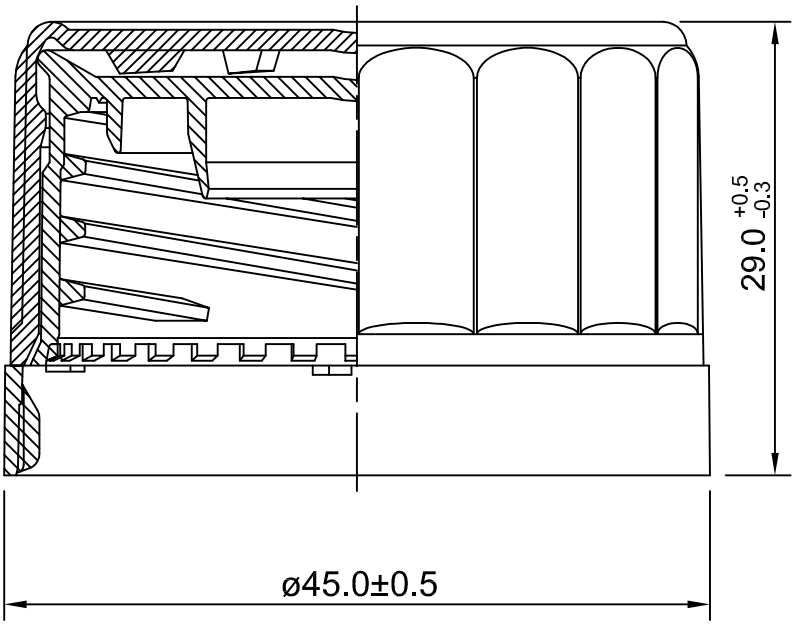
Revisions

Version:	Implementation:	Revision information:
1	2010.02.08	Transfer to new system and additional information
2.1	2010.11.07	Recorrection of version number from 1.0 to 2.1
2.2	2011.01.17	HF840MO Declaration 2011: Updated HF840MO declaration
2.3	2011.05.27	Migr. - HF840MO/PP12455/MAY2011: New migration test
2.4	2011.07.13	HF840MO Declaration 2011: Updated HF840MO declaration HF840MO: Updated Regulation (EU) 10/2011 Clariant PP 12455 White MB: Updated Regulation (EU) 10/2011 CR - Packaging Statement: Updated CR-Packing Statement
2.5	2011.07.14	PP12455 Declaration 2011
2.6	2011.11.16	CR - Packaging Statement: Updated CR-Packaging Statement
2.7	2012.01.31	Registrations and Certifications: More precise description of registrations
2.8	2012.03.21	HF840MO Declaration 2012: Updated
2.9	2012.05.29	IR - HF840MO / PP12455: Updated
2.10	2012.11.22	B03829D-3000: Number of grooves added
2.11	2013.01.09	HF840MO Declaration 2012: Updated
3	2013.01.29	Declaration of Conformity updated
3.1	2013.03.21	HF840MO Declaration 2013: Updated 2013
3.2	2013.04.08	HF840MO Declaration 2013: Updated
3.3	2013.05.24	PP12455 Declaration 2013: Updated
3.4	2013.07.24	IR - HF840MO / PP12455: Updated
3.5	2013.11.08	CR Packaging Statement 2829D, 3829D & 3833D: Updated
3.6	2014.04.23	HF840MO Declaration : With updated EuPh statement (8th edition)
3.7	2014.06.18	WVP updated
3.8	2015.08.28	PP12455 Declaration: Update
3.9	2015.09.17	HF840MO Declaration : Updated
3.10	2015.12.11	CR - Packaging Statement 2829D & 3829D: Updated

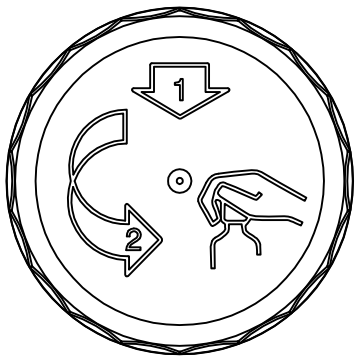
3.11	2016.04.08	Clariant PP 12455: Clariant new company name
3.12	2016.04.18	Clariant PP 12455: Correction of spelling error.
3.13	2016.05.10	Registrations and Certifications: Updated
3.14	2016.06.14	PP12455 Declaration: Updated
4	2016.06.29	Regulatory drawing, Declaration of Conformity and Complaint handling added
4.1	2016.06.29	Quality Control - General text: New classification of defects Quality Control - Duma Twist-Off Cap with CR: Updated
4.2	2016.08.03	IR - HF840MO / PP12455: Updated
5	2016.09.03	USP tests updated
5.1	2016.09.28	HF840MO Declaration : Updated
5.2	2016.09.29	DoC EP (HF 840MO)
5.3	2016.11.10	Physico/In vitro - General: Wording changed
5.4	2016.12.09	PP12455 Declaration: Updated
5.5	2017.02.28	LT - 03829D-3000/OCT2016: Updated
5.6	2017.04.03	Caps VRL: Packed in PE bag
5.7	2017.04.10	HF840MO Declaration : Updated of Medical use statement
5.8	2017.04.26	HF840MO: Update due to USP chapter <661.1>
5.9	2017.05.08	Clariant PP 12455: Updated of supplier name
5.10	2017.05.10	HF840MO Declaration : Update of USP non-compliance statement
5.11	2017.05.15	Added declaration TBA/TCA
5.12	2017.05.23	HF840MO Declaration : Updated with 2017/752
5.13	2017.08.01	Duma T-Off Cap&with Desic.& OneLiner DoC Allergens, Phthalates, BPA,Latex, Melamine: Yearly update
5.14	2017.09.15	Child-Resistant Twist-Off Cap: Updated Child-Resistant Statement 2829D & 3829D: Updated
5.15	2017.10.03	PP12455 Declaration: Updated with 2017/752
5.16	2017.10.05	HF840MO: Approx. instead of about
5.17	2017.10.09	Duma T-Off Cap&with Desic.& OneLiner&Pocket CR DoC Allerg, Phthal, BPA,Latex, Melam: Duma Pocket CR
5.18	2017.10.26	DoC TSE/BSE: Updated (yearly update) DoC EP (HF 840MO): Updated (HF840MO EP non-compliance)
5.19	2018.02.12	HF840MO Declaration : Updated
5.20	2018.05.07	DoC Food Law (HF840MO): Updated
5.21	2018.05.09	HF840MO Declaration : Updated with 79/2018 and 213/2018
5.22	2018.05.15	PP12455 Declaration: Updated with 79/2018 & 213/2018
5.23	2018.05.28	IR - HF840MO / PP12455: Updated
5.24	2018.08.13	HF840MO Declaration : Updated with 2018/831
6	2019.02.04	MVT and Physicochemical test updated
6.1	2019.02.21	DoC Food Law (HF840MO): Updated Registrations and Certifications with FDA,TPD, Russia and China: Updated - China registration.
6.2	2019.03.25	DoC TSE/BSE: Yearly update Duma T-Off Cap&with Desic.& OneLiner&Pocket CR DoC Allerg, Phthal, BPA,Latex, Melam: Yearly update
6.3	2019.03.28	DoC EP (HF 840MO): Yearly update
6.4	2019.04.02	HF840MO Declaration : Updated Medical use statement

6.5	2019.04.30	IR/DSC - General: Text updated
6.6	2019.05.15	IR - HF840MO / PP12455: Updated
6.7	2019.08.02	PP12455 Declaration: Updated with 37/2019
6.8	2019.09.03	Labelling: Updated
6.9	2019.09.05	HF840MO Declaration : Updated with 2019/37
6.10	2019.11.14	PP12455 Declaration: Updated with 2019/1338
6.11	2020.01.28	DoC Food Law (HF840MO): Yearly update
6.12	2020.02.17	Registrations & Certifications update- China registration
6.13	2020.03.24	DoC TSE/BSE: Yearly updated
6.14	2020.04.06	DoC EP (HF 840MO): Yearly update.
6.15	2020.04.14	DoC TSE/BSE: Updated name to Primary Packaging Plastics
6.16	2020.04.15	Registrations and Certifications with FDA,TPD, Russia and new China: Updated name to Primary Packaging Plastics
6.17	2020.04.16	DoC TBA_TCA: Updated
6.18	2020.04.20	DoC EP (HF 840MO): New division name_Primary Packaging Plastic
6.19	2020.04.29	Complaint handling: New division name_Primary Packaging Plastic
6.20	2020.05.19	IR - HF840MO / PP12455: Updated
6.21	2020.08.18	Registrations and Certifications with FDA,TPD, Russia and new China: ISO 45001 obtained
6.22	2020.08.19	Physico - GF4760/HF840MO/Purell 2007H: Updated Physico/In vitro - General: USP 43 <661.2> Registrations and Certifications with FDA,TPD, Russia and new China: Updated with PP caps with desiccant
6.23	2020.08.25	Quality Control - General text: Updated name Primary Packaging Plastics
6.24	2020.09.09	HF840MO Declaration : Medical use and Chemicals, Regulations and Standards statements updated
6.25	2020.09.27	Avient PP 12455: Clariant name change to Avient
6.26	2020.10.19	PP12455 Declaration: Food contact and FDA declarations updated with a new Logo
6.27	2020.11.10	HF840MO Declaration : Food contact declaration updated

2:1



1:1



Replaced drawing		
Designer	Hek	12.01.2015
Released	BS	12.01.2015
Scale	Drawing Type	Size
1 : 1	Regulatory	A4

GERRESHEIMER

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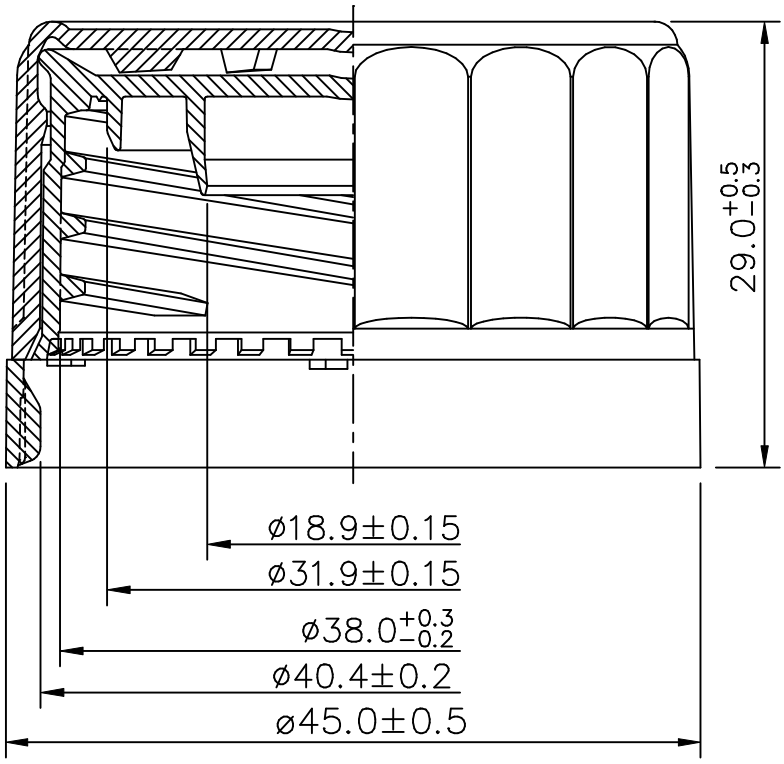
Item
Duma Twist-Off
03829D-3000

No.
A03829D-3000

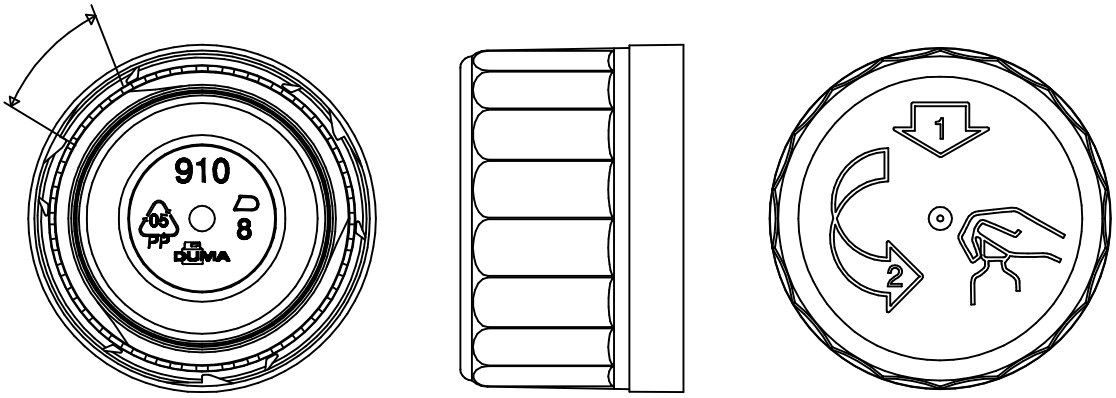
Vers. no.: 1

2:1



Number of grooves from start to first breakpoint: 6–8

1:1



Number of grooves added	06.07.2012	MF	06.07.2012	PH
Logo changed	19.06.2009	JJ	19.06.2009	
No. and logo changed	17.03.2006	JJ	17.03.2006	
Measurements updated	05.2001	PN	05.2001	
Created	12.2000	JJ	12.2000	
Created / Correction	Date	Sign.	Appr. Date	Sign.

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Item	No.
Duma Twist Off 03829D–3000	B03829D–3000
	Vers. no.: 1

Polypropylene
Bormed™ HF840MO

DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS

We confirm that this product fulfils the applicable requirements on substances used for the manufacturing of materials and articles or components of articles intended to come into contact with food as described in the below cited legislation and standards.

EU

The below listed regulations represent harmonised EU legislation and are directly applicable in all EU-member states. National legislation implementing such regulations is therefore not separately cited in this document.

We would like to stress that this product is a **Plastic Intermediate Material** as defined in chapter 4.3.1. of *Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain, from 28.11.2013*. Therefore this confirmation is restricted to the requirements as applicable for **Plastic Intermediate Materials** used for the manufacturing of materials and articles or components of articles intended to come into contact with food.

- Commission Regulation (EC) No 1935/2004. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3 §1,c must be verified and tested by the producer of the final packaging material.
- Commission Regulation (EU) No. 10/2011 as amended. All used monomers and additives are listed in Annex I of this regulation. For any applicable restrictions see chapter “migration testing”.
- Commission Regulation (EC) No. 2023/2006. This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the "Borealis AG responses to customer inquiries" on Borealis' homepage.
- Commission Regulation (EC) No. 1895/2005 - BADGE, NOGE and BFDGE are not used for the production of this grade.
- Commission regulation (EC) No. 450/2009 on active and intelligent materials and articles is not applicable to Borealis' polymer resins.

Additional national legislation in EU-member states (as amended to date)

Polymerisation production aids, aids to polymerisation, colorants and solvents, if not already listed in Annex I of Regulation (EU) No. 10/2011 can be used based on their national approval and are subject to mutual recognition. The process chemicals used for the manufacturing of this grade are permitted by

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Bormed HF840MO

at least one of the following national regulations/recommendations, or are to be deemed safe based on a risk assessment conducted in accordance with article 19 of Regulation (EU) No. 10/2011.

France	Décret No. 2007-766 du 10 mai 2007 portant application du code de la consommation en ce qui concerne les matériaux et les objets destinés à entrer en contact avec les denrées alimentaires, as amended and the French DGCCRF guidelines on food contact plastics.
Germany	BfR-Empfehlung VII Polypropylen, Stand 01.06.2019
The Netherlands	Verpakkingen- en Gebruiksartikelenbesluit, 2014 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amended (last update from 14.12.2019)

Europe (Non-EU-countries)

Norway	Sosial- og helsedepartementets forskrift 1993-12-21-1381 - as amended (referring to Regulation EU No. 10/2011)
Switzerland	Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21) ; Stand 01.12.2019, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff
Turkey	Notification No. 2019/44 from 25.12.2019 - referring to Regulation EU No. 10/2011

World

Brazil	ANVISA RDC nº 56 /2012 - lista positiva de monômeros (Brazilian implementation of Mercosur RES 02/12) ANVISA RDC nº 326/2019 - Lista Positiva de Aditivos (Brazilian implementation of Mercosur RES 39/19)
China	GB9685-2016 - National standard on the use of additives in food containers and packaging materials GB 4806.1-2016 - National standard on general safety requirements for materials and articles in food contact - so far applicable to polymer resins. GB 31603-2015 General Hygienic Standard for Production of Food Contact Materials and Articles - This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the "Borealis AG responses to customer inquiries" on Borealis' homepage. GB 4806.6-2016 - National standard on plastic resins for food contact use - Appendix A - 74 Propylene homopolymer
Japan	Notification No. 196 of 2020 as published on April 28, 2020 by MHLW (Japan Ministry of Health, Labour and Welfare) - and subsequent amendments Appendix 1, Table 1 (1) Basic polymer & Table 1(3) monomers Resin class: 6; all food types; max. temperature: III (> 100°C) Appendix 1, Table 2 Additives All used additives are listed and below the permitted concentration limits
Mercosur	MERCOSUR/GMC/RES. Nº 02/12 - Lista positiva de monomeros MERCOSUR/GMC/RES. Nº 39/19 - Lista positiva de aditivos

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USA	FDA, CFR, Title 21, 177.1520 (a)(1)(i), (b) and (c)1.1a Olefin polymers
Limits of use (FDA)	Test samples made from this product fulfilled the extraction requirements according to FDA CFR 21 §177.1520(c), as defined for the type of polymer described above. Therefore this product may be used in contact with all food types as described in table 1 of CFR 21 §176.170(c), under conditions of use A through H as described in table 2 of CFR 21 §176.170(c) (including articles used for packing or holding food during cooking). **It is the responsibility of the converter or food packer to control that the final packaging complies with the requirements of the intended and foreseeable conditions of use.**

Migration limits and testing

Migration limits	The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Article 6.3.a and Annex II), Mercosur (Res. 39/2019 Annexo 4.3.b) and Switzerland (Bedarfsgegenstände-verordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al). Representative worst case tests (3% acetic acid; 4h/100°C; S/V-ratio 6) did not show any migration above 0,04 mg/kg. Other used monomers and additives are not regulated with specific migration limits. Substances also authorised as direct food additives ("Dual use additives") are either not used for the manufacturing of this product, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceed of the limits as set in the applicable food legislation.
Migration testing	In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21 and article 2.12 of Chinese standard GB4806.1 the overall migration shall not exceed 10 mg/dm² from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg);(Mercosur GMC Res No. 56/92 - 8 mg/dm2 and 50 mg/kg food). **A representative sample from this or a comparable material, tested for 2d at 20°C in isooctane (1 mm plate / total immersion) did not exceed the limit of 10 mg/dm² for overall migration. This test result is only valid for orientation purposes but must not be used to confirm legal compliance of the finished article.** **Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact**

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Polypropylene
Bormed HF840MO

with foodstuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 10/2011; Annex 4 of Swiss Ordinance 817.023.21; Chinese standard GB31604.8-2016; Mercosur GMC Res No. 32/2010. It is the responsibility of the converter or food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

Non-intentionally added substances - NIAS

Commission Regulation (EU) 10/2011 notes that not all contaminants and reaction products of authorised monomers and additives can be listed in its Annex I. The identification of non-listed migrants may therefore not be an exclusion criterion in itself. However, a toxicological evaluation of these migrants 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 recent 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.

Further a variety of representative Borealis products, covering the whole Borealis product spectrum, was assessed in relation to migrating NIAS by renowned test institutes. Beside oligomers the typical NIAS 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 can therefore be rated at least as “Cramer-class III”, allowing a daily consumption of 90 µg/person/day.

However, we wish to stress that a NIAS-assessment is subject to the finished food contact article and the formation of NIAS is influenced by thermal and mechanical treatment during conversion, mixture with other substances and the applied test conditions. A raw material screening therefore can never monitor all potential criteria.

Prepared by Borealis, Group Product Stewardship / Jürgen Emig

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Polypropylene
Bormed HF840MO

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication.

The legislation cited above applies to the final packaging which is intended to come or is brought into contact with foodstuff. This statement however is restricted to the Borealis product as it leaves production. It is the customers responsibility to verify compliance with applicable legislation of the final packaging under actual and foreseeable conditions of use.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

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Polypropylene
Bormed™ HF840MO

STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

We confirm that this product fulfils the requirements on materials used for the manufacturing of articles or components of articles intended for medical use as described in:

Council of Europe	Material complies with the following European Pharmacopoeia monographs: Monograph 3.1.3. Polyolefins: Compliance on all other parts of the monograph with exception of the appearance of solution, absorbance and reducing substances tests. Monograph 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations: Compliance to all other parts of the monograph with exception of the appearance of solution, absorbance and reducing substances tests. Tests are made according to the current Pharmacopoeia edition at the time of the testing: 9th edition (2017), and supplement 9.8 (07/2019). Monograph 3.2.2. Plastic containers and closures for pharmaceutical use: This monograph relates specifically to the container and closure system and does not contain tests that are required for compliance assessment of the raw materials used for said container and closures. The composition of the product is in compliance with this monograph.
Germany	The product follows the VDI 2017 Guideline on “Medical Grade Plastic” that covers the requirements for change management, quality management, supply security and support for regulatory requirements.
USA	Material has passed the following United States Pharmacopeia tests: Biological reactivity tests - in vitro <87>: Cytotoxicity (Elution test) Biological reactivity tests - in vivo <88>: Class VI - 70 °C Physicochemical tests for plastics according to <661>, so far applicable to polymer pellets (with no reference to the specific surface area requirements), including heavy metals, buffering capacity and non-volatile residue test with purified water extract. Plastic materials of construction <661.1>: Identification, physicochemical tests (with exception of absorbance and total organic carbon tests; please contact your Borealis or Borouge representatives for additional information), and extractable metals tests (as listed in the chapter). Plastic additive tests are done according to Borealis’ internal methods. Tests are made according to the current Pharmacopeia edition at the time of the testing (USP 37/39/42).
Additional testing	Material has been tested according to the following ISO 10993 biological tests, in the extent applicable for polymer pellets: Cytotoxicity Acute systemic toxicity

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Bormed HF840MO

	Skin irritation (intracutaneous reactivity) Dermal sensitization Hemocompatibility Tests are made according to the current ISO 10993 edition at the time of the testing (2019).
Elemental impurities	During the manufacturing process of this product, we neither use nor intentionally incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D Guideline on Elemental Impurities (December 2014)
DMF number	Material has been assigned the FDA Drug Master File number(s): DMF 009040
Additional information	If a customer wishes to take advantage of the pre-notice period in case of deletion or modification of Bormed grades, such pre-notice period needs to be included in Technical Delivery Specifications. This edition of the document supersedes any previous editions. Borealis reserves the right to modify this document at any time, so please ensure to view it frequently. Changes to this document may be made with or without notice. Please always ensure that you are viewing the latest edition by downloading documents directly from our website at www.borealisgroup.com.
Prepared by	Borealis, Group Product Stewardship / Aino Haritonova

Disclaimer

The product(s) mentioned herein are not intended for use as medical implant material or implantable medical devices and we do not support their use for such applications.

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.

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It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

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BOREALIS

Polypropylene
Bormed™ HF840MO

STATEMENT ON CHEMICALS, REGULATIONS AND STANDARDS

We certify that during manufacturing of this product we do not use or intentionally add any of the chemicals restricted by the following regulations and standards and their subsequent amendments in amounts which exceed the applicable limits.

- Annex XVII of the REACH Regulation 1907/2006/EC - Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles
- Annex XIV of the REACH Regulation 1907/2006/EC - List of substances subject to authorisation
- CONEG "Toxics in Packaging" Model Legislation, rev. 2008
  Directive 94/62/EC (Packaging and packaging waste - PPW) and related EN13428 and CR13695
  - Sum of Cd, Cr, Hg and Pb < 100 ppm
- Directive 2000/53/EC (End of life vehicles - ELV) - Cr(VI), Hg and Pb < 0.1 wt%, Cd < 0.01 wt%)
- Directive 2011/65/EU (Restriction of the use of certain Hazardous Substances in electrical and electronic equipment - ROHS) and all other ROHS legislations worldwide that restrict some or all of the following substances - Cr(VI), Hg, Pb, PBB, PBDE, DEHP, BBP, DBP, DIBP < 0.1 wt%, Cd < 0.01 wt%
- Directive 2012/19/EU (Waste Electrical & Electronic Equipment - WEEE) - Annex VII - No ingredients used which require selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated FR)
- Proposition 65 list of Chemicals Known to the State of California to Cause Cancer or Reproductive Toxicity - no warning labels are required for this product
- Regulation 1005/2009/EC (Substances that deplete the ozone layer)
- US Clean Air Act, Title VI, Classes I and II (EPA Final Rule; Federal Register 8136, 11.2.1993) on substances that deplete the ozone layer
- Regulation (EU) 2019/1021 on persistent organic pollutants (POPs), repealing 850/2004/EC
- Regulation 1169/2011/EU - Annex II (allergens)
- Global Automotive Declarable Substance List (GADSL) and VDA232-101
  - No use of prohibited or declarable substances above threshold limits
- Swiss SR 814.018 (Verordnung über die Lenkungsabgabe auf flüchtigen organischen Verbindungen - VOCV) - VOC's according to Annexes 1 & 2 < 3 wt%
- Regulation 1223/2009/EC "on cosmetic products" - prohibited and restricted substances
- Directive 2009/48/EC (safety of toys)
- European Standard EN 71-3:2013+A3:2018 "Safety of Toys", Part 3: "Migration of certain elements" - Migration below limits for toy material category III in Table 2, and EN 71-9:2005+A1:2007 "Organic chemical compounds - Requirements" (Tables 2 A-I).
- Japanese CSCL; Class I and II Specified Chemical Substances
- Japanese PRTR law; Class I or Class II Designated Chemical Substances

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Polypropylene
Bormed HF840MO

Regarding classification of the above product according to REGULATION (EC) No 1272/2008 and its subsequent amendments, reference is made in the SDS/PSIS for the above product.

We also certify that during the manufacturing of the above product we do not use or intentionally incorporate into it any of the following materials:

Acrylamide
Antimony, Arsenic, Beryllium, Bismuth
Aromatic Amines (restricted in Regulation 1907/2006/EC, Annex XVII)
Artificial Musks
Asbestos
Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII)
Azodicarbonamide, semicarbazide
Benzophenones (e.g. 4-MBP, 4-HBP, 2,2´-Dimethoxy-2-phenylacetophenone)
BHA or BHT
Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides)
Bisphenols and their compounds (e.g. NOGE, BFDGE, BADGE)
Cadmium, Chromium (VI), Lead, Mercury
CFC, HCFC
CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC
Colophony (rosin)
4,4'- Diaminodiphenylmethane (MDA)
Di-2-ethyl-hexyl maleate (DEHM)
Dimethylfumarate (DMF), Dibutylfumarate
1,4-Dioxane
Endocrine disruptors: Category 1 substances in the European Commission EDS database
2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams
Flame retardants (halogenated or phosphorus based)
Formaldehyde
Fragrances
Furfural
Glycol ethers (e.g. EGME, EGMEA, EGEE, EGEEA)
Glyoxal
Gold, Indium, Nickel, Palladium
Halogenated organic compounds
Melamine, Cyanuric acid
MOAH (mineral oil aromatic hydrocarbons)
Nanomaterials (>50% of particles <100 nm)
Natural rubbers, Latex
Nitrosamines, Nitrates, Nitrites
Octyl- and Nonylphenols and Octyl- or Nonylphenolethoxylates; TNPP
Organotin compounds
Parabens
PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
PFAS (e.g. PFOA, PFOS)
Phthalates
Plasticisers (e.g. Adipates, ESBO, Phthalates)
Polychlorinated Bi-, Terphenyls and Naphthalenes
Polychlorinated dibenzodioxins and dibenzofurans
Polycyclic aromatic hydrocarbons (PAH) as restricted in Regulation 1907/2006/EC, Annex XVII
Quaternary ammonium compounds
Radioactive substances
Recycled materials
Silicones (polysiloxanes)
Selenium, Silver, Tellurium, Thorium
Styrene, Polystyrene
SVHC on "Candidate List of Substances of Very High Concern for Authorisation"
Thiuram mix
Tin, Gold, Tantalum, Tungsten
UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
Vinylchloride, Vinylidenechloride, PVC or PVDC

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Polypropylene
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The substances used in the manufacturing of the above product, and if applicable the basic polymer(s), are listed in the following chemical inventories:

Australia/AICS
Canada/DSL
China/IECSC
Europe/EINECS or ELINCS or NLP
Japan/ENCS
Korea/KECL
New Zealand/NZIoC
Philippines/PICCS
Taiwan/TCSI
USA/TSCA (all relevant ingredients designated as active)

Prepared by Borealis, Group Product Stewardship / Barbara Lindorfer

Disclaimer

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Polypropylene

Bormed™ HF840MO

INFORMATION ON USP NON-COMPLIANCE

Bormed HF840MO has been tested to the new chapter <661.1> of USP 39 and was found not to be compliant to the absorbance and total organic carbon test requirements. These tests were not required in the chapter <661> of USP 38 to which the product had been previously tested.

Bormed HF840MO contains a slip agent as part of its functional additivation. Internal tests have shown that the water solution of Bormed HF840MO contains this slip agent and this is believed to be the reason for the non-compliance of the two tests.

Following information can be given about the slip agent:

- Not classified as hazardous according to the Regulation (EC) No. 1272/2008 (CLP)
- Listed on the 'positive additive list' of the European Pharmacopoeia and can be used in the formulation up to 0,5 wt-% in polypropylene containers
- Can be used without restrictions for food contact applications according to the EU and US food contact regulations

The significance of this non-compliance has to be determined on the final article. Borealis can support the assessment by disclosing, subject to a Secrecy Agreement, the formulation of the resin. Please contact your Borealis or Borouge representatives for assistance.

Prepared by Borealis, Group Product Stewardship / Aino Haritonova

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BOREALIS

Polypropylene

Bormed™ HF840MO

STATEMENT ON ORIGIN OF RAW MATERIALS

Animal based materials and BSE/TSE
In this product we incorporate small amounts of stearates or other materials derived from fatty acids. These are derived from fat that can be of animal origin. Our polymer additive suppliers guarantee the following:

- The fat is only derived from Category 3 materials as laid down in Regulation No (EC) 1069/2009 (Animal by-Product Regulation)

- Additives are manufactured under conditions exceeding the rigorous requirements described in the Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev. 3): *Transesterification or hydrolysis at not less than 200 ºC for not less than 20 min under pressure.*

Further, the plastic material is exposed to temperatures above 200 ºC for several minutes during the extrusion step in the plastic manufacturing process. Under the described conditions any virus, bacteria or substance causing immunological diseases (TSE; BSE, CJD) is destroyed. We therefore state that our product is to be considered safe with respect to BSE and TSE transmissions.

Genetically modified organisms (GMO)
We certify that manufacturing this product, we do not use or intentionally add into it any substances derived from genetically modified organisms.

Halal certification
This product does not have an official Halal certification.
In this product we incorporate small amounts of substances of animal origin and therefore the suitability of this product cannot be guaranteed.

Kosher certification
This product does not have an official Kosher certification.
In this product we incorporate small amounts of substances of animal origin and therefore the suitability of this product cannot be guaranteed.

Palm oil, palm kernel oil and their derivates
In this product we incorporate small amounts of stearates or other materials derived from fatty acids. These are derived from vegetable oils that can be of palm oil or palm kernel oil origin.

Prepared by Borealis, Group Product Stewardship / Aino Haritonova

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BOREALIS

Polypropylene
Bormed HF840MO

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It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

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Avient

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0000145632 33923988 08.10.2020

Declaration

WHITE MB PP 12455

Introduction

This declaration applies exclusively to the above-mentioned product when used as colouring or additive agent of a plastic food contact material and article. Our mixture is not intended to come directly in contact with food in its original form: therefore, since Avient has no influence on subsequent processing, this declaration cannot be extended to the finished material or article. Indeed, the compliance of the end material or article with the food contact regulations is the responsibility of the converter. He is committed to meet all relevant legal requirements and to test the migration limits according the conditions of use (temperature, time, simulants) of the article in its finished form (e.g. volume, geometry, thickness). These conditions are not part of our knowledge and therefore are not under Avient's control.

Framework Regulation (EC) No. 1935/2004 and GMP Regulation No 2023/2006

Framework Regulation (EC) No. 1935/2004 sets out the general rules that must be met by all classes of food contact materials without giving any specific rule of how to prove the safety of food contact articles: plastic materials are covered by specific measures in relation to component types used in the formulation of our mixtures:

- polymers and additives are regulated by Regulation (EU) No 10/2011 and its amendments.
- colourants (including dyes, organic and inorganic pigments) must not migrate and must also comply with the purity requirements laid down in the national laws of Member States. General requirements for colourants are listed in the EU Resolution of the Council of Europe, AP (89) 1 though this is not legally binding.
- catalysts, solvents and polymer production aids (not yet listed at EU level) shall be assessed with general rules of the Framework Regulation by the substance manufacturer and/or shall comply with the national legislations provisions.

The product is not expected to cause any contravention to the Framework Regulation since the subsequent stages of manufacture, processing and distribution of the end article are in line with the Good Manufacturing Practices (GMP) applicable to food contact materials and article's supply chain, as listed in Regulation (EC) No 2023/2006. In addition, we would declare that our own production process, as a part of this supply chain will conform to the provisions of GMP.

Hereafter the status of the different component types is given according to their applicable legislation and based on the declarations received by Avient from starting materials suppliers:

Commission Regulation (EU) No 10/2011 and its amendments

All the carriers and the intentionally added additives comply with the requirements of Regulation (EU) No 10/2011 and its amendments published before the release date of this certificate. We would like to remind you that the assessment of overall migration limit, other release restrictions such as those found in Annex II (the release of aromatic amines in a detectable quantity and the specific migration limits for all metals, especially considering low migration limits established) is the responsibility of the producer of the finished article

(converter).

Restrictions and Limitations

- Aluminium: SML = 1 mg/kg food or food simulant

- N,N-Bis(2-hydroxyethyl)alkyl(C8 - C18) amine : SML(T) = 1.2 mg/Kg expressed as tertiary amine, see note (7) Annex I / Table 2.

Additional information
Please note, that some SMLs concern additives present in the above mentioned preparation.

Please note, that the following dual-use-additives are contained:
FCM number / name of the additive / content of the additive (given in range)

610	Titanium dioxide	40 - 60 %
575	Polydimethylsiloxane (Mw > 6800 Da)	0,1 - 0,25 %
9	Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	not available
116	Benzoic acid & salts	not available
504	Silicon dioxide	0,5 - 1 %

SML	Specific Migration Limit	SML(T)	Specific Migration Limit expressed as Total
DL/LR/NG	Detection Limit	FP/PF/BG	Finished Product or Article

European Resolution AP (89) 1

All the colourants used meet the requirements established in European Resolution AP(89) 1 in regard to the maximum permissible levels of heavy metals, primary aromatic amines, sulphonated aromatic amines and polychlorinated biphenyls.

Belgium: Arrêté Royal from 11.05.1992 of the Moniteur Belge 24.07.1992

All the colourants used meet the purity requirements listed in the Arrêté Royal from 11.05.1992 of the Moniteur Belge 24.07.1992 and its amendments.

France: Jorf

All the colorants fulfil the applicable requirements and restrictions for food contact applications.

Germany: BfR Recommendation IX

There are no objections to the use of the colourants in this product according to the Recommendation IX of the BfR (Federal Institute for Risk Assessment).

Italy: Decreto Ministeriale

All the colourants used, meet the purity requirements listed in the Decreto Ministeriale of 21.03.1973 and its amendments.

The Netherlands: Warenwet

All the colourants used meet the purity requirements listed in the Dutch regulation Warenwet and its amendments.

Spain: Real Decreto 847/2011 (subsecretaria para Sanidad)

All the colourants used meet the purity requirements listed in Annex II of Real Decreto 847/2011 (subsecretaria para Sanidad) and its amendments.

Turkey: Food Codex Regulation

All the components used meet the requirements of Turkish Food Codex Regulation on Materials and Articles in Contact with Foodstuffs issued in April 5th, 2018 and its amendments.

We would also like to inform you of the status of our product in regard to the Directive 94/62/EC, CONEG (Regulation status and the content of diarylide pigments):

Directive 94/62/EC, CONEG and Heavy Metals

Heavy metals and/or their compounds are not intentionally added by us during production and, on the base of our present knowledge, they are not contained (or are present just as impurity at trace-level) in raw materials which are used for the production of above-mentioned product. In any case, our company does not carry out any specific analysis in order to detect the presence of above mentioned substances and then this statement is based on specific information provided by our raw material suppliers. The product meets the requirements of the EC Directive 94/62/EEC and the CONEG regulation which limits the content of heavy metals up to 100 ppm (Cd, Pb, Hg, Cr(VI)).

Diarylide Pigments

The product does not contain any intentionally added diarylide pigment in its chemical composition.

Clariant Plastics & Coatings (Polska) Sp. z o.o.

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0000145632 33923989 Version : 1 - 5 08.10.2020

Declaration

WHITE MB PP 12455
Material number: PC02175008

Introduction

This document is intended to provide information on the current status of the above-referenced material under certain regulatory programs. Please review this document carefully and contact your Avient representative if you have any questions.
All statements refer exclusively to the named product in its current formulation: they are based on the present state of our knowledge and experience and concern the product in its original form and packaging as supplied from our factory.
Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field. Due to the broad range of possible applications we make no warranty that the actual use of the product in the finished article is comprised by the information below.

Hereafter the status of the different component types is given according to their applicable legislation and based on the declarations received by Avient from starting materials suppliers:

USA Food and Drug Administration

In the USA substances used as a component of articles intended to come into contact with food are regulated by Food and Drug Administration FDA 21 CFR Title 21. Specific limitations and conditions of use, as set forth in these regulations, are specified below.

The components entering into the formulation of the above-referenced product are approved under one or more of the specific FDA paragraphs or have other clearances listed below:

1. Colorants listed in 21 CFR 178.3297 "Colorants for Polymers."

2. Components that are exempt from regulation under 21 CFR 170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
3. Polymers and/or additives listed in the appropriate parts of 21 CFR (174, 175, 176, 177, 178, 181, 182, 184 and 186).
4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
6. Substances that are "Prior Sanctioned" for use in this application.
7. Substances that are the subject of applicable Food Contact Substance Notifications.

Condition of Use and Restriction:
No further regulatory restraints, food type limitations or restrictions of conditions of use (as listed from A through H into title 21 CFR, §176.170(c), table 2) apply to this material. Material may not be used at levels greater than that required to achieve the desired intended technical effect in the food contact article.

Directive 94/62/EC and CONEG

Based on the knowledge of the raw materials as well as of the manufacturing process this product meets the requirements of the Directive 94/62/EC and the CONEG regulation which limits the content of heavy metals up to 100 ppm (Cd, Pb, Hg, Cr(VI)).

Diarylide Pigments

The product does not contain any intentionally added diarylide pigment in its chemical composition.

Clariant Plastics & Coatings (Polska) Sp. z o.o.

FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE OF ANY PRODUCT OR SERVICE.

9/2010

Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

31448918 06.02.2019

Declaration

WHITE MB PP 12455

Introduction

All statements refer exclusively to the named product in its current formulation: they are based on the present state of our knowledge and experience and concern the product in its original form and packaging as supplied from our factory.
Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field.

Additional information

- Based on the current formulation of the above mentioned product, we inform you that its formulation contains:

  Traces of phthalates

- Based on the current formulation of the above mentioned product, the following substances have not been intentionally added during its production:

  Bisphenol A, Latex, Melamine, Allergens

  These substances were not used as starting materials during the mixing phase of our product but, on the basis of our current knowledge, we cannot give you any warranty they are not constitutionally contained (or are present at level of ubiquitous(**) traces) in raw materials. Please note that, in any case our Company does not carry out any specific analysis in order to detect the presence of above mentioned substances.
  (**)Ubiquitous in regard to a chemical substance means that this substance is omnipresent (occurs literally everywhere) and its occurrence in this "ubiquitous" traces cannot be avoided by any technical, physical or chemical measure.

Additional information

In addition be informed that, in case here above was not clearly mentioned, you can find the following information into the Safety Data Sheet you already got by us:
– the ingredients that may be classified as dangerous for health and environment;

- information on restriction on use that we are aware of and that could be relevant for plastic applications.

Clariant Plastics & Coatings (Nordic) AB

Country Product Stewardship

This declaration was produced automatically and therefore does not have an original signature

This information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. Clariant makes no warranties, express or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of Clariant's products for its particular application. Nothing included in this information waives any of Clariant's General Terms and Conditions of Sale, which control unless it agrees otherwise in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing Clariant products, are available upon request and are provided in compliance with applicable law. You should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact Clariant.

* For sales to customers located within the United States and Canada the following applies in addition:
NO EXPRESS OR IMPLIED WARRANTY IS MADE OF THE MERCHANTABILITY, SUITABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE OF ANY PRODUCT OR SERVICE.
9/2010

Anna Wisniewska
Gerresheimer Boleslawiec S.A.

PL -
Poland

32359304 24.09.2019

Declaration

WHITE MB PP 12455

Introduction

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Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field.

Additional information

- Based on the current formulation of the above mentioned product, we inform you that its formulation contains:

  Traces of Phthalates, < 15 ppm

Additional information

In addition be informed that, in case here above was not clearly mentioned, you can find the following information into the Safety Data Sheet you already got by us:
- the ingredients that may be classified as dangerous for health and environment;
- information on restriction on use that we are aware of and that could be relevant for plastic applications.

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This declaration was produced automatically and therefore does not have an original signature

This information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. Clariant makes no warranties, express or

implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of Clariant's products for its particular application. Nothing included in this information waives any of Clariant's General Terms and Conditions of Sale, which control unless it agrees otherwise in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing Clariant products, are available upon request and are provided in compliance with applicable law. You should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact Clariant.

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9/2010

05.02.2019

Declaration

WHITE MB PP 12455 (PC02175008)

Introduction

All statements refer exclusively to the named product and its current formulation as supplied from our factory in its original form and packaging and are based on the present state of our knowledge and experience.
Since the masterbatch manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use and to ascertain the compliance of the end article with the national and international regulations and laws concerning its application field.

BSE/TSE:

Based on the knowledge of the raw materials as well as of the manufacturing process, we are able to confirm that the product does not contain intentionally added components of animal origin. They are not used by us during production and, on the base of our present knowledge, are not contained (or are present just as impurities at trace-level) in raw materials which are used for the production of our preparations; please note that in any case, our Company does not carry-out any specific analyses in order to detect the presence of the a.m. substances.

Clariant Plastics & Coatings (Nordic) AB
Box 9053
SE-200 39 Malmö
Phone: +46 40 671 72 00
E-mail: psmalmo@clariant.com
Web: www.clariant.com

Additional Information

The information given in the present declaration is based on the current level of our knowledge, and is intended to provide information about our products. It should therefore not be construed as guaranteeing specific properties. Buyer or user are responsible for ensuring that the products they use, as supplied by us, comply with the specific requirements of their intended application.
Due to the progress (evolution) of national and international regulations and laws the status of the above mentioned product could eventually change. If you have any doubt relating to the current correctness of this declaration, please contact us for an update.

Clariant Plastics & Coatings (Nordic) AB

Tine Tornqvist Tosun
Product Stewardship

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Clariant Plastics & Coatings (Nordic) AB
Box 9053
SE-200 39 Malmö
Phone: +46 40 671 72 00
E-mail: psmalmo@clariant.com
Web: www.clariant.com

Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

31489294 15.02.2019

Declaration

WHITE MB PP 12455

Introduction

All statements refer exclusively to the named product in its current formulation: they are based on the present state of our knowledge and experience and concern the product in its original form and packaging as supplied from our factory.
Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field.

Additional information

- Based on the current formulation of the above mentioned product, the following substances have not been intentionally added during its production:

  Any of the substances mentioned in ICH Q3D Guideline for Elemental Impurities

  These substances were not used as starting materials during the mixing phase of our product but, on the basis of our current knowledge, we cannot give you any warranty they are not constitutionally contained (or are present at level of ubiquitous(**) traces) in raw materials. Please note that, in any case our Company does not carry out any specific analysis in order to detect the presence of above mentioned substances.
  (**)Ubiquitous in regard to a chemical substance means that this substance is omnipresent (occurs literally everywhere) and its occurrence in this "ubiquitous" traces cannot be avoided by any technical, physical or chemical measure.

Additional information

In addition be informed that, in case here above was not clearly mentioned, you can find the following information into the Safety Data Sheet you already got by us:
- the ingredients that may be classified as dangerous for health and environment;
- information on restriction on use that we are aware of and that could be relevant for plastic applications.

Clariant Plastics & Coatings (Nordic) AB

Country Product Stewardship

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9/2010

Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

32547352 07.11.2019

Declaration

WHITE MB PP 12455

Introduction

All statements refer exclusively to the named product in its current formulation: they are based on the present state of our knowledge and experience and concern the product in its original form and packaging as supplied from our factory.
Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field.

Additional information

- Based on the current formulation of the above mentioned product, the following substances have not been intentionally added during its production:

  Nitrosamines

  These substances were not used as starting materials during the mixing phase of our product but, on the basis of our current knowledge, we cannot give you any warranty they are not constitutionally contained (or are present at level of ubiquitous(**) traces) in raw materials. Please note that, in any case our Company does not carry out any specific analysis in order to detect the presence of above mentioned substances.
  (**)Ubiquitous in regard to a chemical substance means that this substance is omnipresent (occurs literally everywhere) and its occurrence in this "ubiquitous" traces cannot be avoided by any technical, physical or chemical measure.

Additional information

In addition be informed that, in case here above was not clearly mentioned, you can find the following information into the Safety Data Sheet you already got by us:
- the ingredients that may be classified as dangerous for health and environment;
- information on restriction on use that we are aware of and that could be relevant for plastic applications.

Clariant Plastics & Coatings (Nordic) AB

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TEST REPORT

Client

Gerresheimer Vaerloese
Walgerholm 2-8
DK-3500 Vaerloese
Denmark

Report No 728779/21
1347624
27 March 2017
HEAL

Specifications

Closure

Type:	Duma Twist-Off Cap
Number:	03829D-3000
Raw material:	HF840MO (PP)
Colour:	White, PP 12455
Cavity:	13-36 (mould 3)

Container

Type:	Duma Twist-Off 250 ml
Number:	045256-3000
Raw material:	GF4760 (PE-HD)
Colour:	White, PL00075542 (PE)
Cavity:	3-6 (mould 1)

Test period: 10 March 2017 – 24 March 2017

Classification: Moisture Vapour Transmission

10 specimens of containers and closures have been tested according to USP 39 <671>. Classification for packaging systems, the containers so tested are *tight containers* if not more than one of the *10 test containers* exceeds 100 mg per day per litre in moisture vapour transmission, and none exceeds 200 mg per day per litre. Packaging systems are *well closed* if not more than one of the 10 test containers exceeds 2000 mg per day per litre in moisture vapour transmission, and none exceeds 3000 mg per day per litre.

The work has been carried out according to the General Terms and Conditions regarding commissioned work accepted by the Danish Technological Institute.

Results

mg water vapour per day per litre container-volume:

No 1	No 2	No 3	No 4	No 5	No 6	No 7	No 8	No 9	No 10
2.1	2.0	2.1	2.1	2.0	2.1	2.0	2.0	2.1	2.1

Average: 2.0 mg/d/l

Conclusion
The tested containers comply with the classification of USP 39 <671> test for tight containers.

Centre: Packaging and Logistics

Helle Allermann, Senior Consultant
Phone: +45 72 20 31 63
e-mail: heal@dti.dk
Test responsible

Stanislav Landa, Consultant
Phone: +45 72 20 16 54
e-mail: stal@dti.dk
Co-reader

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TEST REPORT

Client

Gerresheimer Vaerloese
Walgerholm 2-8
DK-3500 Vaerloese
Denmark

Report No 718850/9
5 October 2016
1347624
HEAN

Specifications

Closure

Type:	Duma Twist-Off Cap
Number:	03829D-3000
Raw material:	HF840MO (PP)
Colour:	White, PP 12455
Cavity:	13+25 (Mould 3)

Date of receipt:	29 September 2016
Test period:	29 September 2016

Light Transmission

Closure has been tested according to USP 39 <671> - according to test requirements for containers.
Requirement: The light transmission must not exceed 10 % in the range from 290 to 450 nm. Enclosure 1 shows the spectra from 290 to 450 nm of the samples from the closure.

Results

maximum % light transmission:

Sample No 1	Sample No 2
2.7	1.9

Conclusion
The tested closure complies with the requirement of USP 39 <671>.

Centre: Packaging and Logistics

Helle Antvorskov, Senior Consultant
Phone: +45 72 20 31 69
e-mail: hean@dti.dk

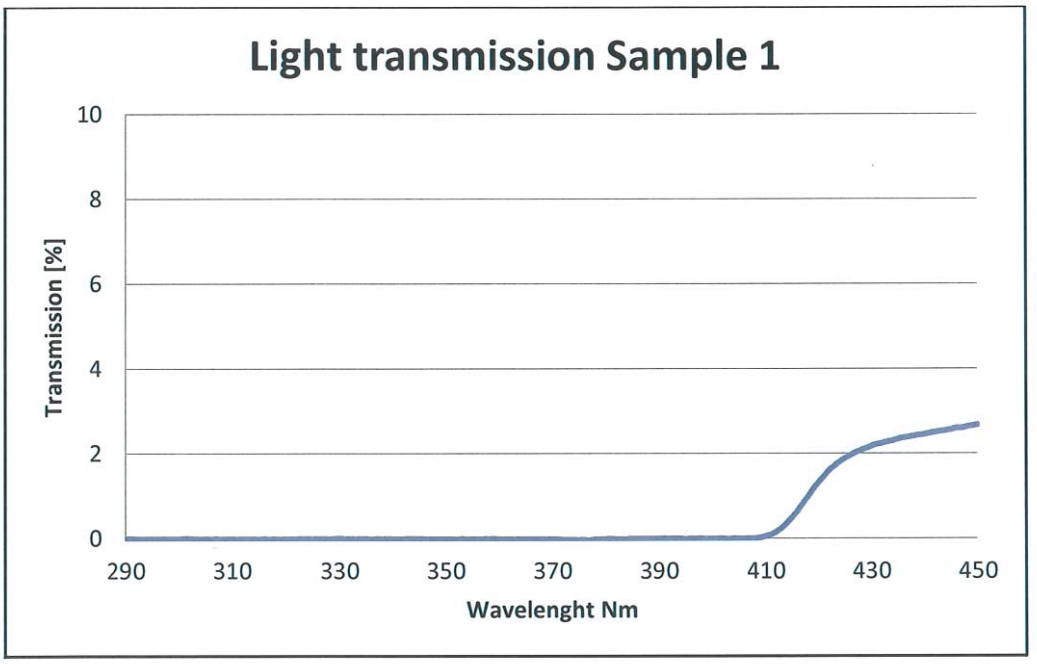
Test responsible

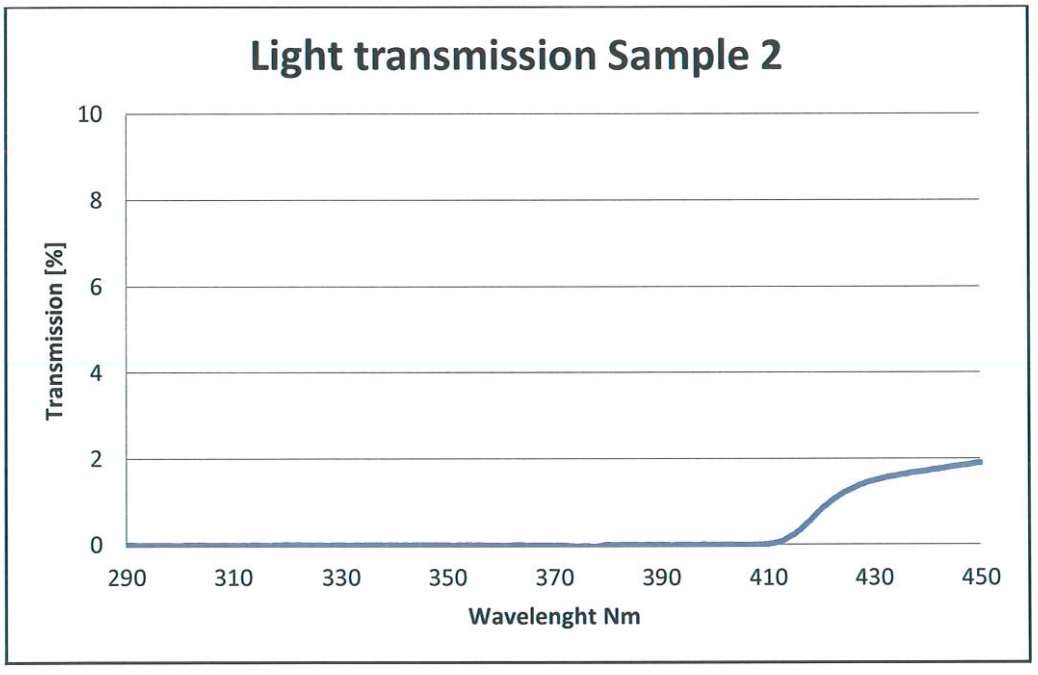
Stanislav Landa, Consultant
Phone: +45 72 20 16 54
e-mail: stal@dti.dk

Co-reader

Gerresheimer Vaerloese

Type: Duma Twist-Off Cap
Number: 03829D-3000





Child-Resistant and suitable for senior adults

Gerresheimer Vaerloese A/S
Walgerholm 2-8
3500 Værløse, Denmark

Duma Twist-Off Cap 2829D & 3829D

ISO 8317 (2003)
The Institute for Ergonomics and IVM Institut VerpackungsMarktforschung GmbH confirms that the Duma Twist-Off Cap 2829D & 3829D on Duma Twist-Off Container 15 ml – 600 ml and Duma Twist-Off Q Container 30 ml – 200 ml are certified according to ISO 8317 (2003). The package obtained the confirmation of conformity after a formal test procedure according to ISO 8317 (2003).

The package is also in compliance with ISO 8317 (2015) as no modifications have been made to the packages since they were tested against ISO 8317 (2003).

C.F.R. Title 16, Part 1700.20
Results of a study performed by Institute of Ergonomics demonstrate that the Duma Twist-Off Cap 2829D & 3829D on a Duma Twist-Off Container 15 ml (035015-3000) & 400 ml (045406-3000) and on a Duma Twist-Off Q Container 30 ml (Q35030-3000) & 200 ml (Q45200-3000) fulfill the standards for child-resistant effectiveness and for senior adult use effectiveness (SAUE) according to current C.F.R. Title 16, Part 1700.20.

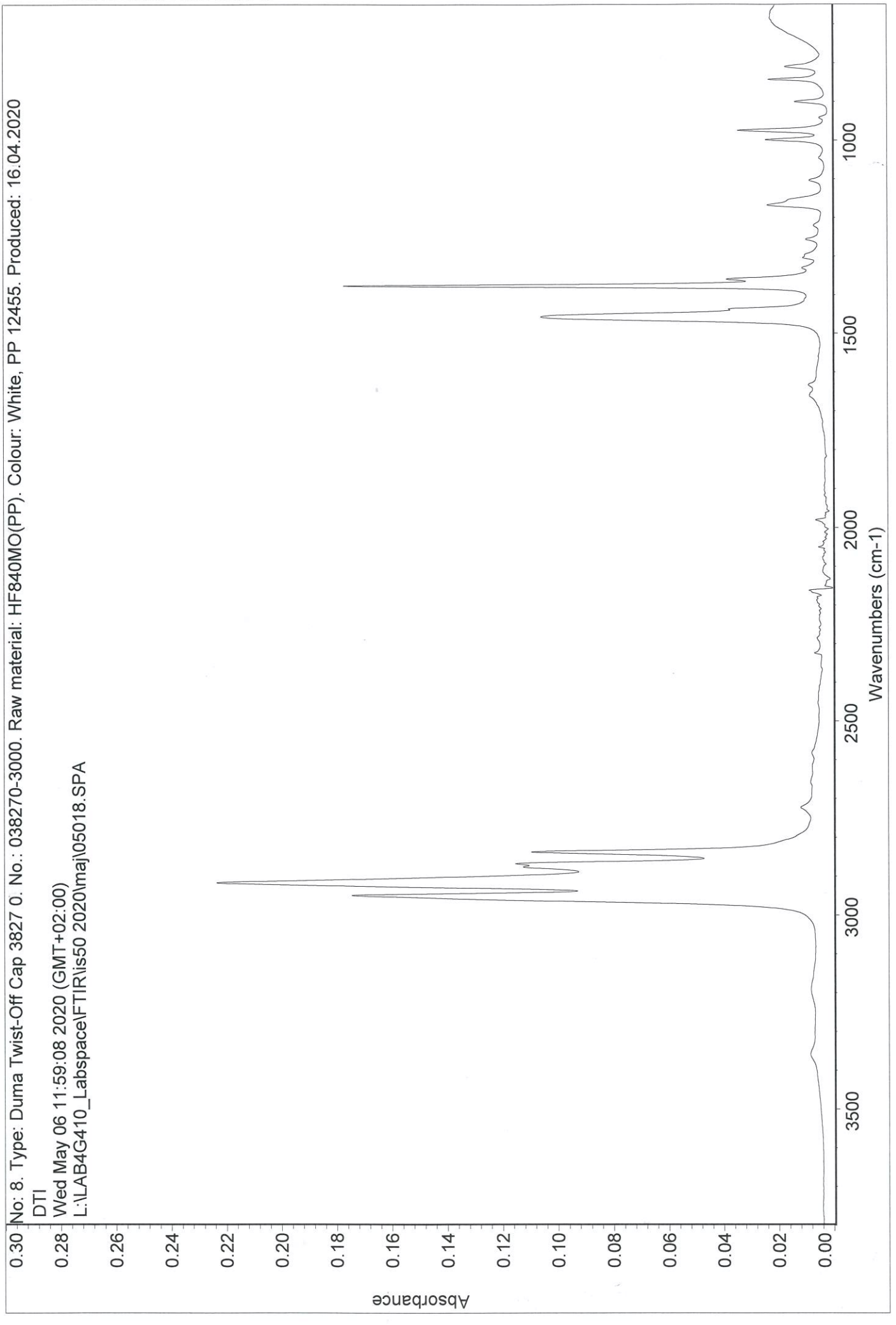
The other containers in the Duma Twist-Off range which can be used together with the Duma Twist-Off Cap 2829D & 3829D have not been tested according to C.F.R. Title 16, Part 1700.20 – however they are identical with regard to dimensions on the neck and thread.

It is the responsibility of the customer of the packaging system to evaluate/conclude if further testing is required. Test reports can be provided upon request.

For products being released after conduction of the above described tests, an internal documented evaluation is performed in order to ensure that the new products are either covered by existing tests or new tests will be performed.

Værløse, September 13th, 2017

Christina D. Holder
Quality Manager


No: 8. Type: Duma Twist-Off Cap 3827 0. No.: 038270-3000. Raw material: HF840MO(PP). Colour: White, PP 12455. Produced: 16.04.2020
DTI
Wed May 06 11:59:08 2020 (GMT+02:00)
L:\LAB4G410_Labspace\FTIR\is50 2020\maj\05018.SPA
Absorbance
0.30
0.28
0.26
0.24
0.22
0.20
0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
3500
3000
2500
2000
1500
1000
Wavenumbers (cm-1)

DANAK

TEST Reg. no. 127

1 August 2016
ten-decr

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Test report

Customer

Gerresheimer Vaerloese A/S
Walgerholm 2-8
DK-3500 Vaerloese

Rep. no.: 139/16-3

No. of encl.: 1
Cosign:

Test

Thermal analysis

Sample

Raw material sent to our laboratory on 22 June 2016 bearing the following ID

DSC sample no. 3
Raw material: HF840MO (PP)
Batch no.: B1-60075

DSC sample no. 4
Raw material: PPH 10012 (PP)
Batch no.: 630272

DSC sample no. 5
Raw material: PPC 10712 (PP)
Batch no.: 630158

Test method

The DSC (thermal analysis) is based on

USP 39 <661> *Containers - Plastics / Physical Tests*, which refers to
USP 39 <891> *Thermal Analysis*

One spot sample (approx. 12 mg) was taken from the raw material.
The following conditions were used for the comparative DSC analysis:

Heating 25 °C to +200 °C at 10 °C/min in nitrogen (80 ml/min)
Hold the temperature for 10 min at 200 °C
Cooling 200 °C to 110 °C at 10°C/min in nitrogen (80 ml/min)

The peak values of the Onset temperature are compared.

DANISH TECHNOLOGICAL INSTITUTE

Test equipment

32T07.02	Calorimeter, Differential Scanning Calorimetry, DSC 823e from Mettler-Toledo
32T14.60	Analytical balance XS 105 from Mettler-Toledo
32T07.03	Reference sample of polypropylene from USP (Rockville)
Purge gas	Nitrogen (purity grading: 5) from Aga

Test results

Sample	Melting Peak °C	Onset °C	Difference between values (Onset temperature) °C
Ref sample of polypropylene	166.0	153.7	-
DSC sample no. 3 Raw material: HF840MO (PP) Batch no.: B1-60075	168.5	154.8	1.1
DSC sample no. 4 Raw material: PPH 10012 (PP) Batch no.: 630272	168.0	153.7	0
DSC sample no. 5 Raw material: PPC 10712 (PP) Batch no.: 630158	169.1	154.8	1.1

Acceptance criteria: Difference between values (Onset temperature) ≤ 12.0 °C
Test result: *Pass*

Yours sincerely
Centre for Plastics Technology

Tina Elmer Nielsen
Laboratory Technician

Phone: +45 72 20 31 13 (direct)
Email: ten@teknologisk.dk

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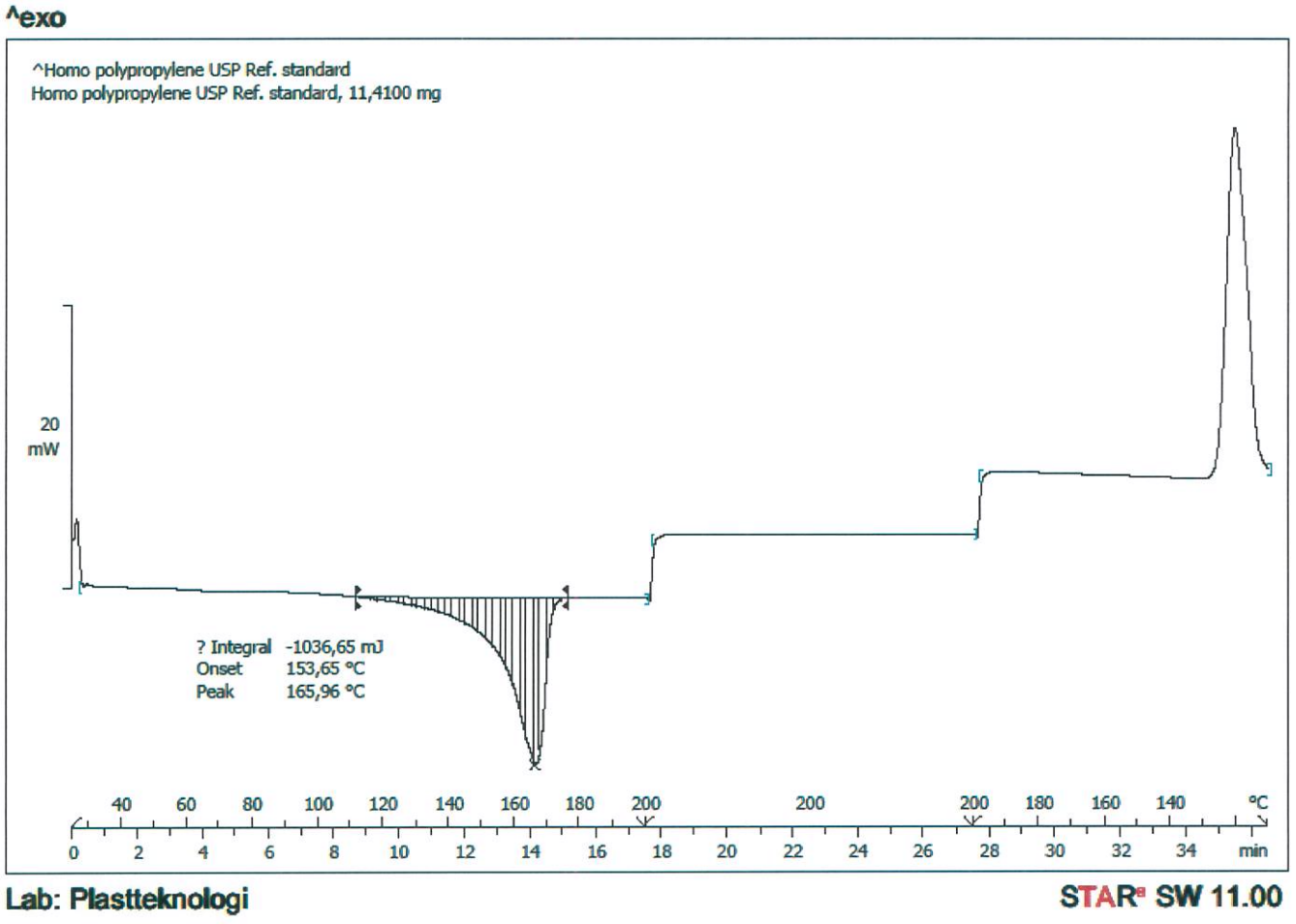

Ref sample of polypropylene

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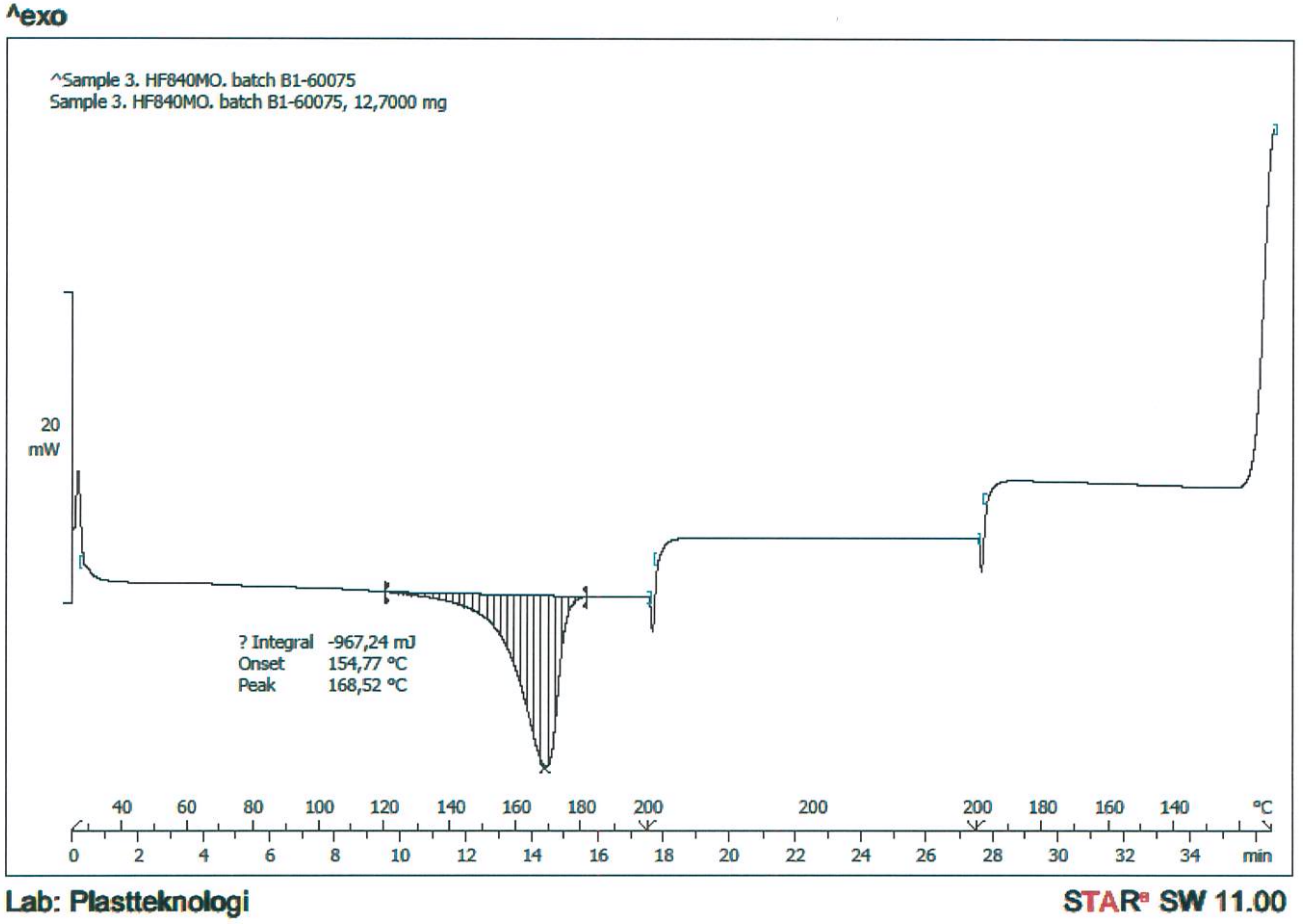

DSC sample no. 3
Raw material: HF840MO (PP)
Batch no.: B1-60075

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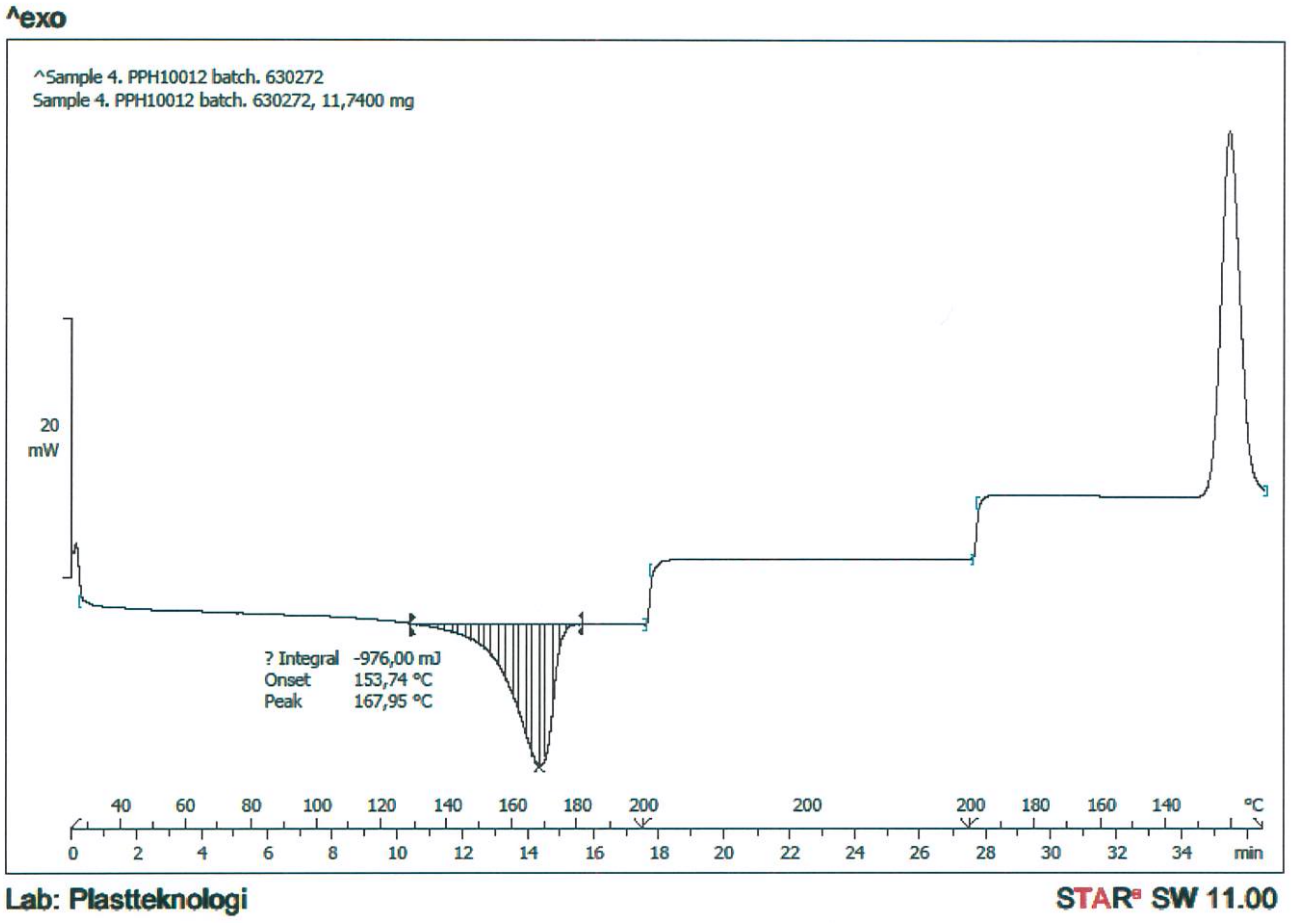

DSC sample no. 4
Raw material: PPH 10012 (PP)
Batch no.: 630272

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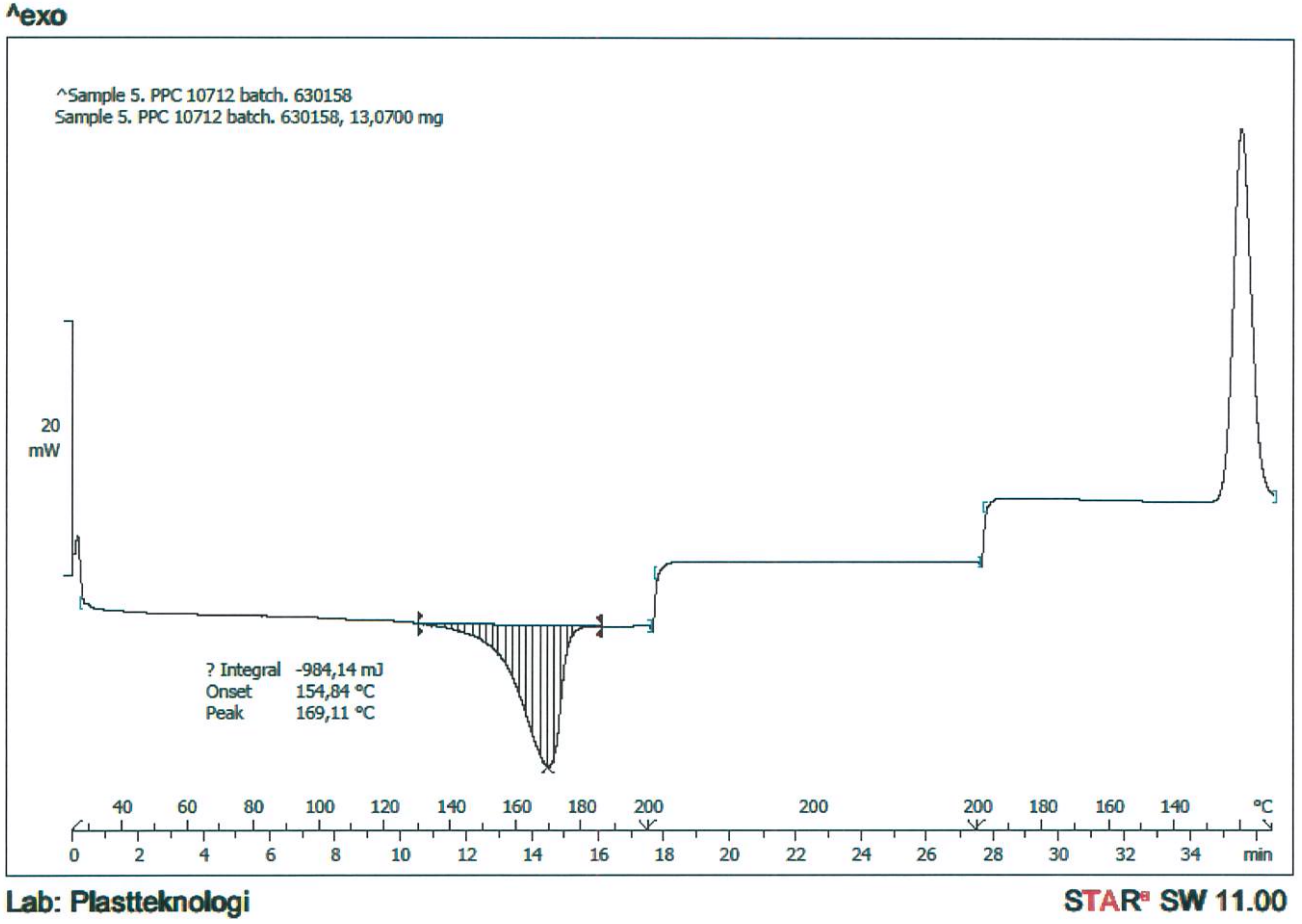

DSC sample no. 5
Raw material: PPC 10712 (PP)
Batch no.: 630158

Nelson Labs.
A Sotera Health company

TEST RESULT REPORT

TE202033/ 20-B9814

Material: Twist-Off Container (60 mL) with Twist-Off Cap and Desiccant

Lot: GF4760 + HF840MO + Purell 2007H

TESTS ON PLASTIC PACKAGING SYSTEMS FOR PHARMACEUTICAL USE - USP 43 NF 38

CHAPTER: 661.2

Client: Gerresheimer Vaerloese A/S

Contact: Mr. René Palmelund

Address: Walgerholm 2-8

3500 Vaerloese

Denmark

Client Purchase Order Number: 15191

Quotation Number: 2004165

Date Receipt Samples: 06 Jul 2020

Date Start Analysis: 23 Jul 2020

Date Technical Release: 30 Jul 2020

Date Final Test Result Report: 14 Aug 2020

REFERENCES:

United States Pharmacopoeia 43 NF 38, Chapter 661.2 section "Physicochemical Tests".

Iris Persy
Study Director

Stijn Nulens, Ing.
Quality Assurance Unit

Nelson Labs nv - Romeinsestraat 12 - B-3001 Leuven - Belgium - nelsonlabs.be
Office Phone: +32 16 40 04 84 - Fax: +32 16 40 13 04 - BTW BE 0442.395.719 - RPR Leuven
JPM IBAN BE13 5490 0105 9839 - BIC CHASBEBX (EUR Payments)
JPM IBAN BE88 5490 0106 0041 - BIC CHASBEBX (USD Payments)

RESULTS:

The results are presented in Table 1.

Table 1: Results of Analysis

Test	Results	Evaluation Criteria	Meets Criteria
Appearance of Solution C1	Clear, no color	Solution C1 is clear and colorless	PASS
Absorbance	≤ 0.20 A.u.	Maximum Absorbance between 230 nm to 360 nm ≤ 0.20 A.u.	Meets Specification
Acidity	+ 0.4 mL 0.01N NaOH → colorless to pink	≤ 0.4 mL of 0.01N NaOH → colorless to pink	PASS
Alkalinity	+ 0.8 mL 0.01 N HCl → pink to orange-red	≤ 0.8 mL of 0.01N HCl → pink to orange-red	PASS
TOC	≤ 8 mg/L	Maximum difference between sample and blank TOC ≤ 8 mg/L	Meets Specification

CONCLUSION:

Based on the evaluation criteria mentioned above, the test material *complies with the limits* of the United States Pharmacopoeia 43 NF 38, Chapter 661.2 section "Physicochemical Tests", *and meets the specifications* for "Absorbance" and "TOC".

TOXIKON
ADVANCING YOUR INNOVATION

ISO 17025 BELAC 363 - TEST

TEST RESULT REPORT: 16-B3703-N1

Project Number:	**TE161161**	**Report Date:**	**30/06/2016**
Sponsor:	**Gerresheimer Vaerloese A/S**		
Contact Person:	*René Palmelund*		
Address:	Walgerholm 2-8	Date Sample Arrival:	15/06/2016
City, State, Zip:	3500 Vaerloese	Technical Initiation:	27/06/2016
Country:	Denmark	Technical Completion:	30/06/2016

Study:	**Qualitative MEM-elution: Dye exclusion**	Temp/Time	37°C/24 hours
Test article name:	**03827D-3000**	Ratio	4g/20mL
Lot number:	**Sample 10**	Vehicle	MEM-Complete

REFERENCE: According to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices- Part 5:Tests for In Vitro Cytotoxicity." and "USP 39-NF 34, 2016: <87> Biological reactivity test, in vitro." Toxikon Reference: SOP 3.1.2.3, rev. 10

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. The sample and control articles were autoclaved prior to the preparation of the extracts. Extracts were prepared at 37±1°C for 24±2 hours in a humidified atmosphere containing 5±1% carbon dioxide (static). Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The maintenance medium on the cell cultures is replaced by the extracts of the test item or control article in triplicate and the cultures are subsequently incubated for 2 days, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Biological reactivity was rated on the following scale: Grade 0 (No reactivity); Grade 1 (Slight reactivity), Grade 2 (Mild reactivity), Grade 3 (Moderate reactivity) and Grade 4 (Severe reactivity). The test item is considered to have no cytotoxic potential if none of the cultures exposed to the test item shows greater than mild reactivity (Grade 2).

RESULTS: No reactivity (Grade 0) was exhibited by the cell cultures exposed to the test item at the 2 days observation. Severe reactivity (Grade 4) was observed for the positive control article. The negative control article showed no signs of reactivity (Grade 0).

OPINION AND INTERPRETATION: Based on the evaluation criteria mentioned above, the test item is considered to have no cytotoxic potential.

RECORD STORAGE: All raw data generated in this study will be archived at Toxikon Europe, according to SOP 4.2.8.

AUTHORIZED PERSONNEL

01 JUL 2016
Ms. Vanessa Ruymen
Study Director

04 JUL 2016
Ms. Anja De Schouwer
Quality Assurance

Running-in of Duma Twist-Off Closure

When running-in a closure from the Duma Twist-Off Closure series, the closure must be handled as a new closure. This is whether or not the filling line has previously handled other closures from the Duma Twist-Off series.

When running-in the Duma Twist-Off Closure on an existing filling line, make sure:

- that the closure is mounted correct and ensure tightening with the container
- that the closure is not stripped and in this way damaged or that the container is damaged, and
- that the closure is not screwed too deep on the container as this might cause deformations

Therefore we recommend that running-in, tests and validation are performed on the filling line and in the process, even though the filling line has handled other closures of the Duma Twist-Off series before.

Concrete observations

During the validation it is important that the person, who is mounting the closure, is aware of the fact that a too low adjusted torque might influence the tightness of the packaging as the closure will only have contact with the container with the sloping area of the sealing ring. This means that the tension, which creates tightness between the closure and the container will be missing, i.e. the closure has not been screwed tight enough on the container.

Contrary if the torque is too high the top of the closure will be squeezed off as the top of the container neck will squeeze against the inner of the closure and the flexibility, which is built into the curvature in the top of the closures, will be exceeded and the closure will break, i.e. the closure has been screwed too tight on the container.

We must draw the attention to the fact that some engine fitters are able to adjust the speed of screw. Experience shows that a too high speed of screw combined with a too high torque makes the closures break.

Therefore it is important that the validation contains both speed of screw and torque and that you try to obtain the settings on which both parameters are as low as possible in respect of the tightness of the packaging.

Other matters

In case of further questions, please contact your daily sales contact in order to clarify these questions.

02 December 2015
Technical Support

Quality Control

The quality assurance system of Gerresheimer Plastic Packaging is oriented towards a “zero defect strategy”. AQL values for dimensions must be within agreed specified limits. The necessary safety with respect to avoidance of dimensions out of specification (OOS) is achieved by means of process validation including risk analysis and/or in-line measurements and/or measurements on samples.

AQL values are defined on attributive characteristics according to below classification.

Classification of defects

Classification of defect	Effects of defects	Defect class	AQL Containers / Caps		Consequence
Critical	Critical defects are defects whose presence can have critical consequences. They can, for example: • endanger human life or health • or violate legal requirements • or lead to destruction or alteration of filling material • or seriously impair the reliability of storage • or seriously impair the efficiency of production tools, filling and packaging equipment	1	(*)	(*)	Packaging material not usable
Major	Major defects are defects whose presence can lead to considerable impairment. They can, for example: • lead to inefficient function and thus to deficiency of the packaging material/pack • or lead to consumer complaint • or lead to reduced efficiency in production • or impair the efficiency of production tools, and filling and packaging equipment	2A	0.25	0.1	Usability of packaging material markedly impaired
		2B	1.0	0.4	Usability of packaging material moderately impaired
Minor	Minor defects are defects whose presence do not have essential consequences, for instance they • represent a reduction in general quality	3	4.0	2.5	Usability of packaging material slightly impaired

(*) No AQL value is defined for defect class 1 since for this defect class, tests are done against zero defects with the greatest possible certainty and/or manufacturing process is to be correspondingly validated.
The necessary safety with respect to the avoidance of critical defects class 1 is achieved by means of process validation measures including risk analysis and/or in-line inspection and system checks. If defects of class 1 are found, it must be determined whether the entire batch or part of the batch is affected.

If a partial quantity containing a critical, major or minor defect can be clearly and reliably separated, the quality of the remainder of the batch must be evaluated separately.

AQL values for Duma Twist-Off Cap with CR

Defects	Defect class
- Raw material, primary packaging material or labelling not according to specification - Mix-up - CFU exceeds specification - Shelf life exceeded - Moisture vapour transmission or light transmission or multiple internal reflectance or differential scanning calorimetry or physicochemical or biological reactivity – in vitro <87> OOS according to USP or EP - Migration testing exceeds requirements for food contact material - Contamination inside, contamination outside - can get into content - Tears, clefts, holes, parts incompletely moulded - usability or tightness not ensured - Defects on sealing points - tightness impaired - Engraved/embossed text is missing or incorrect - Threads from injection point - can be detached - 4-6 bridges on sealing ring are broken - Child resistant does not function - Individual parts missing	1
- Foreign bodies incorporated in the material - Contamination outside on product - cannot get into product - Inhomogeneous colour - Deformation, parts incompletely moulded - usability markedly impaired - Defects on sealing points - tightness not impaired - Injection point too high - Flashes - usability markedly impaired - Uneven surface - Burn marks > 2 mm - PE - Bags with holes or incorrectly closed - Opening force or application force outside specification	2A
- Burn marks ≤ 2 mm - Notches and clefts and roughness - Flashes - usability moderately impaired - Threads from injection point - cannot be detached - 3 bridges on sealing ring broken	2B
- 1-2 bridges on sealing ring are broken - usability slightly impaired	3

If a carton is damaged or soiled upon arrival, the error should be noted at arrival on the shipping documents and the carton discarded. The remaining part of the batch is to be received as normal goods.

Quality control for Duma Twist-Off Cap with CR

Activity	Control
Incoming control of raw materials	Identification of goods received and control of certificates.
Set-up new mould or change of raw materials or control specification	**Line clearance** including control of correct use of raw materials. One sample of each cavity produced at the same time is visually controlled as well as checked for critical dimensions with plug-and ring gauges by production and QC prior to production start.
Production	QC operator performs a **visual control** of the products in accordance with ISO 2859-1. The samples are taken every second hour (one sample per cavity produced at the same time). A sample of each cavity is checked for critical dimensions with plug-and ring gauges. New approval by production and QC is required after **machine stops** lasting more than one hour. In case of unplanned machine stops where components can be defected the products are 100% controlled or scrapped. If defects are detected, components are quarantine stored or 100% controlled.
Quality control	QC **reviews all the production documentation** and point out components that need additional control. This also includes follow-up on components which are quarantine stored by production. QC **controls the dimensions** of the samples from two of the in-process controls with plug-and ring gauges. They also perform a **function test** by mounting, open and re-closing the system. The samples are from two different shifts. QC releases the components for assembly.
Set up new article number or control specification in assembly department	**Line clearance** is performed. Samples are visually controlled by production prior to production start.
Assembly of caps and mounting of desiccants	QC operator performs **a visual control** of the products in accordance with ISO 2859-1. The samples are taken every second hour. If there is a **machine breakdown** a new approval by production is required. In case of machine breakdown where products can be defected the products are 100% controlled or scrapped. If defects are detected, products are quarantine stored or 100% controlled.

Quality control	QC **reviews all the production documentation** and point out products that need additional control. This also includes follow-up on products which are quarantine stored by production. QC performs a **function test** by mounting, open and re-closing the system. The samples are from two different shifts. The **opening force** is measured daily. Additional tests are performed when required. QC controls the pallets for mix-up and incorrect labelling, releases the products and issue certificates with the results of the controls.

Measurement of Opening Force (Torque)

Caps are mounted on a container and measured by a torque tester according to valid instruction.

Release criteria:

- Average of the results must be within defined specification +/- upper and lower limit
- A maximum of 15% of the individual items must exceed 10% of the upper or lower limit
- A maximum of 10% of the individual items must exceed 20% of the upper or lower limit

Gerresheimer Vaerloese A/S · Walgerholm 2-8 · DK-3500 Vaerloese · Denmark

April 14, 2020

Declaration of Conformity

European Pharmacopoeia (EP)

Declaration concerns all products with the following composition:

- **HF840MO & White masterbatch**
- **HF840MO & White masterbatch & Liner**
- **HF840MO & White masterbatch & Molecular Sieve & Bottom Foil**
- **HF840MO & White masterbatch & Silica Gel/Molecular Sieve & Bottom Foil**
- **HF840MO & White masterbatch & Silica Gel & Bottom Foil**

Supplier of resin only confirms that resin fulfill monograph 3.1.6 Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations but only as to composition of polymer and maximum limits of additives. According to information from supplier and based on their observations, some of batches have failed the test of appearance of solution and absorbance but some have passed the tests. Additionally, supplier informed about non-compliance of resin the reducing substances tests from monograph 3.1.6. due to the more stringent pass criteria of the test (<0,5 ml) compared to the monograph 3.1.3 Tests results are affected by the presence of slip and the results are inconsistent. The results are available upon request.
According to declaration from the supplier of the resin, slip agent is not classified as hazardous, according to the Regulation (EC) No. 1272/2008 (CLP). Additionally, from food contact side there are no restrictions for the use of this additive in EU or US.

The masterbatch, Silica Gel, Molecular Sieve, Liner and Bottom Foil used during production comply with the relevant regulations related to plastic materials intended to come into contact with food however the suppliers do not declare the materials to be in compliance with the European Pharmacopoeia.

Gerresheimer Vaerloese A/S · Walgerholm 2-8 · DK-3500 Vaerloese · Denmark

Gerresheimer Vaerloese A/S additionally informs that our packages dedicated for solid oral dosage forms and solid active substances are tested in accordance with food law. For such substances, it has been agreed by the Joint Committee for Medicinal Products for Human Use / Committee for Medicinal Products for Veterinary Use Quality Working Party that plastic materials compliant with the relevant European Union (EU) food legislation relating to plastic materials and articles intended to come into contact with foodstuffs are considered acceptable.

Yours sincerely,

Anna Wiśniewska

Regulatory Affairs Manager
Primary Packaging Plastics

GERRESHEIMER

DECLARATION OF CONFORMITY

Gerresheimer Vaerloese A/S
Walgerholm 2-8
3500 Værløse, Denmark

European Union (EU) Food Contact

Based upon the certificates from our suppliers of resins and masterbatches, product tests and our certified Quality system, Gerresheimer Vaerloese A/S hereby confirms that the below listed products comply with relevant requirements of Regulation (EC) No 1935/2004 (Framework Regulation) on materials and articles intended to come into contact with food, Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food and Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as amended inclusive Regulation (EU) 2019/37.

- **Duma Twist-Off Caps with or without desiccant – white coloured products**
- **Duma OneLiner – white coloured products**

The intended use for the above listed products is storage of medicine and foodstuff as powder and tablets without fatty surface according to the product specification. Shelf life is 5 years without desiccant, 2 years with a silica gel desiccant and 1 year with a molecular sieve desiccant.

The products have been tested for contact with dry food to long time storing at room temperature.

A functional barrier made from plastic is not used in the above-mentioned products.

In contrast to specific migration testing where volatile migrants adsorbed onto simulant E can be analysed specifically without losing them, for overall migration testing a gravimetrical determination is applied to the extract of simulant E with the consequence that migrants previously adsorbed to simulant E are largely lost again during evaporation of the solvent. Therefore foods, for which only simulant E is prescribed by the Regulation, are not subject to overall migration limit testing.

When used as specified, tests have shown that the specific migration does not exceed the legal limits.

The formulation of the raw materials used for the production of the concerned products contains the below listed substance considered to be a dual-use substance according to Regulation (EU) No 10/2011:

Duma Twist-Off Cap and Duma OneLiner:
- Titanium dioxide – FCM no 610
- Polydimethylsiloxane – FCM no 575
- Benzoic acid & salts – FCM no 116
- Acids – FCM no 9

Duma desiccant insert:
- Silicon dioxide – E551
- Titanium dioxide – FCM no 610
- Polydimethylsiloxane – FCM no 575

The products contains components with Specific Migration Limit:

Duma Twist-Off Cap and Duma OneLiner:

• Cas no. 7429-50-5	Aluminium	SML = 1 mg/kg
• PM ref 39090	Atmer	SML(T) = 1.2 mg/kg

Duma desiccant insert:

• Cas no. 7429-50-5	Aluminium	SML = 1 mg/kg

The migration tests have been performed according to Regulation (EU) No. 10/2011 (Annex V):

- Test conditions (contact time above 30 days at room temperature):
  - 10% ethanol / 10 days / 60°C by total immersion

- Surface to volume ratio:
  - 10% ethanol: 1.99 dm^2 / 100 ml (Duma Twist-Off Cap & Duma OneLiner)
  - 10% ethanol: 1.98 dm^2 / 100 ml (Duma desiccant insert)

USA Food and Drug Administration and US Pharmacopoeia (USP)

Based upon certificates from our suppliers of resins and masterbatches, we state compliance of Bormed HF840MO & Purell 2007H with relevant parts of FDA title 21 CFR § 177.1520 and of PP 12455 White MB & Remafin-pe White E PE0CAB12020 with relevant parts of FDA title 21 CFR §§ 177.1520 & 178.3297.

The products comply with the requirements defined in the USP in relation to the following tests:

- <661> Single Internal Reflectance
- <661> Differential Scanning Calorimetry
- <661> Physicochemical test
- <671> Moisture Vapour Transmission
- <671> Light Transmission

Værløse, January 27, 2020

Christina D. Holder
Quality Manager

GERRESHEIMER

April 14, 2020

Declaration of Conformity

Primary Packaging Plastics requires from all raw materials suppliers to inform about any animal derived substances used for production of their products and also requests from suppliers to consider and fulfill the relevant regulations of the European Community about the avoidance of TSE/BSE contamination.

If applicable, all suppliers are requested to fulfil the requirements:

- The animal derived substances used for the manufacturing of their polymers are either produced from animals originating from BSE-free countries or are free from SRM (specified Risk Material).
- The manufacture of the animal derived substances involves rigorous processes that meet/exceed the very severe process conditions for inactivating any BSE/TSE agent.

If any of raw materials contain ancillary materials based on fatty acid, such fatty acids might have a number of origins from for example plants, animal or synthetic, where the animal origin is the most common. The use of these subsidiaries as ancillary materials, including packaging for the pharmaceutical - and the foodstuff industries, are regulated through a number of EU directives. Tallow derived materials used in some product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3". These directives regulate the general use of these products and specifically security against BSE to transmit to pharmaceutical - or foodstuff products.

Primary Packaging Plastics has received statements or certificates from all suppliers, where they state that:

- their products do not contain specific material of risk (SRM) and that infection does not transmit via their products, or
- their products fulfilled all requirements laid down in relevant regulations concerning BSE/TSE substances.

Yours sincerely,

Katarzyna Jawor
Compliance Specialist
Primary Packaging Plastics

GERRESHEIMER

March 22, 2019

Declaration of Conformity

Declaration concerns the following products:

- Duma Twist-Off Cap
- Duma Twist-Off Cap with Desiccant
- Duma OneLiner
- Duma Pocket CR

Gerresheimer Plastic Packaging only process the raw materials delivered from the suppliers and do not add any additional materials to such raw materials. Based upon the certificates from the suppliers of the raw materials, Gerresheimer Plastic Packaging hereby confirms that:

- Melamine
- Bisphenol A
- Latex
- Allergens

have not been intentionally added during their production. However, the fact that these substances are not used in these products it does not exclude that trace levels of them may be present as a result of the specific characteristics of the raw materials and/or of the manufacturing process. Please note that, in any case suppliers do not carry out any specific analyses in order to detect the presence of the above mentioned substances.

- Phthalates

The supplier of masterbatch PP12455 informed that formulation of this product contains traces of phthalates.
Based on information from the rest of suppliers of raw materials used in manufacture of above mentioned products, Gerresheimer Plastic Packaging hereby declares that phthalates have not been intentionally added during their production.

The information is given to the best of our knowledge and does not include any warranty whatsoever. It must therefore not be misunderstood as guaranteeing specific properties.

Yours sincerely,

Jasińska

Wioleta Jasińska
Junior Compliance Specialist
Gerresheimer Plastic Packaging

GERRESHEIMER

DECLARATION OF CONFORMITY

Gerresheimer Vaerloese A/S
Walgerholm 2-8
3500 Værløse, Denmark

Gerresheimer Vaerloese A/S has taken appropriate precautions to reduce the risk for TBA (2,4,6-tribromoanisole) and TCA (2,4,6-trichloroanisole) contamination of products supplied to our customers.

TBA with a threshold of 0.02 PPT and TCA with a threshold of 1 PPT do not introduce any toxicological risks but can have impact in musty molded odor.

Risk for TBA/TCA contamination is included into the risk analysis for the whole manufacturing and handling/storage process in the plant and all wooden pallets used for raw materials, component and final products are heat treated and comply with ISPM 15.

Gerresheimer Vaerloese A/S can only be held responsible for any odor issues due to TBA and/or TCA contamination, if it can be proven that the contamination of the primary plastic packaging has happened before shipment of the products.

Værløse, April 16th, 2020

Christina D. Holder
Quality Manager

Customer Complaint Report

GERRESHEIMER

❒ Complaint ❒ Comment / Remark Customer report No:	Established by / date:
Customers name / address / country:	Contact person / E-mail / Fax no.:
Article no.:	Date of delivery:
Batch no.:	Invoice no.:
Cavity no.:	Order no.:
Number of defective items:	Total quantity delivered:
Defect observed in: ❒ Incoming control……. Sample size: ❒ Production…….. Quantity of items used: ❒ Final product(s)…….. Quantity of items used: ❒ Complaint from end-user	
Defect found in: ❒ One carton ❒ Several cartons: Quantity _____	Exact production date/time from carton/bag or carton/bag/pallet number: ❒ Not available
Are filled/not filled products quarantined: ❒ Yes – Quantity (filled): ❒ Yes – Quantity (not filled): ❒ No ❒ N/A – no products left	Samples: ❒ Will be send ❒ Not available ❒ Additional information will be forwarded
Description of defect:	

Received by QA dept. (init. / date): _____

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Labelling

Company name:	Today's date:
❒ Wrong information ❒ Missing information ❒ Missing label ❒ Label difficult to read	
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
The defect is observed in ❒ One bag/carton ❒ Several bags/cartons - Quantity	
Exact production date and time for all concerned bags	
Exact quantity of defective items/bags/cartons	
How many bags/cartons have been controlled	
Amount of products blocked	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Loose silica gel / loose desiccant / defect on desiccant

Company name:	Today's date:
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
Defect observed in: ❒ Upon reception at your warehouse ❒ Incoming inspection - sample size/plan:_____ ❒ Observed in PDS ❒ Before filling/when opening the cartons ❒ Before filling/on your line ❒ After filling ❒ Market complaint	
Defect observed in ❒ One bag ❒ Several bags - Quantity	
Exact production date and time for all concerned bags	
Exact quantity of defective items	
Are there any signs of damage to cap, desiccant or cardboard	
Are there any signs of transport damage to bag or carton	
Quantity of item used or controlled from the batch	
Amount of products blocked	
Amount of filled products blocked	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Mix-up

Company name:	Today's date:
Ordered product	
Product received	
How many bags/cartons have been controlled	
Amount of products blocked	
Production date and time of all the concerned bags/cartons	

❒ Samples have been send
❒ Samples will be send
❒ Pictures are available
❒ No samples or pictures are available

For for mix-up - both carton label and bag label is important – and it would be helpful, if the pictures also showed the production date/time.

Comments:

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Partly- or disconnected TE-rings

Company name:	Today's date:
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
Quantity of caps with disconnected TE-rings	
Quantity of caps with partly disconnected TE-rings *Please specify quantity of broken bridges according to the AQL values/specification.*	
Specific cavity number affected	
Defect observed in: ❒ Incoming inspection - sample size/plan:_____ ❒ Observed in PDS ❒ Before filling/when opening the cartons ❒ Before filling/on your line ❒ After filling ❒ Market complaint	
Quantity of item used or controlled from the batch	
Amount of products blocked	
Amount of filled products blocked	
Defect observed in ❒ One bag/carton ❒ Several bags/cartons - Quantity	
Exact production date and time for all concerned bags	
Are there signs of damage to the cap/bag/carton	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Product defect

Company name:	Today's date:
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
Defect observed in: ❒ Upon reception at your warehouse ❒ Incoming inspection - sample size/plan:_____ ❒ Observed in PDS ❒ Before filling/when opening the cartons ❒ Before filling/on your line ❒ After filling ❒ Market complaint	
Exact quantity of defective items	
Specific cavity number affected	
Quantity of item used or controlled from the batch	
Amount of products blocked	
Amount of filled products blocked	
Defect observed in ❒ One bag ❒ Several bags – Quantity	
Exact production date and time for all concerned bags	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Transport

Company name:	Today's date:
❒ Pictures are available ❒ No pictures are available	
❒ A copy of the CMR ("Proof of delivery" from the transporter) has been forwarded ❒ A copy of the CMR ("Proof of delivery" from the transporter) will be forwarded ❒ The CMR ("Proof of delivery" from the transporter) is not available	
Defect observed on ❒ One carton ❒ Several cartons	
Exact quantity of damaged cartons	
Products can be used	❒ yes / ❒ No
Comments:	