# **Food contact**

## **Total Opening Drums**

## 1. DoC issued by

Company: CurTec International B.V.

Address: P.O. Box 25

5120 AA Rijen The Netherlands

Contact: regulatory.affairs@curtec.com

## 2. Products manufactured by

Company: CurTec Nederland B.V. Address: Spoorlaan Noord 92

5121 WX Rijen The Netherlands

## 3. Product identity

Total opening drums, consist of a drum and a lid. The screw lid contains a mounted sponge rubber sealing gasket.

Drum	Capacity	Lid
6945	17 litre	6950
6947	26 litre	6950
6950	34 litre	6950
6948	39 litre	6950
6946	52 litre	6950
6942	55 litre	6970
6943	64 litre	6970
6944	75 litre	6970
6990	90 litre	6990
7392	100 litre	7140
6994	110 litre	6990

For substances in used polymers see 6a and 6b.

For substances in used colorants see annex colorants.

## 4. Issue date

25 August 2021, based on specification of used materials dated 01 July 2016



#### 5. EU regulatory status - Total opening drums

EC regulation 1935/2004

Total opening drums comply with the safety aspects set out in Article 3(1)(a) of the Framework Regulation (EC) 1935/2004.

#### **GMP**

Total opening drums are being produced in accordance with the relevant requirements of Commission Regulation (EC) 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.

## Traceability

CurTec has systems in place fulfilling the relevant aspects on traceability as required in article 17 of Regulation (EC)1935/2004.

#### Recycling

The product is not subject to regulation (EC) 282/2008, based on article 1, 2b.

## Active and intelligent packaging materials

The product does not fall under the regulation for Active and Intelligent packaging materials, (EC) 450/2009.

#### 5a. Used monomers and additives

Products have been manufactured only with monomers, other starting substances and additives that are authorized under the Plastics Regulation (EC) 10/2011 (up to and including the amendment (EC) 2020/1245).

#### 5b. Other materials/substances used in the formulation

Only colorants are added by CurTec to the polymer. No additional additives are added by CurTec.

## 5c. Inks, coatings, adhesives and colorants

Inks, coatings or adhesives are not used.

Declaration of compliance on colorants can be found in the Annex, numbered by color code.

## 5d. Handles

The handles and connecting parts on CurTec drums are not considered food contact parts. The handle and it's connecting parts are made of the same materials as the drum and lid. Used black coloring master batches are suitable for food contact, according to the Annex of coloring materials.

#### 5e. Sealing gasket

The sealing gasket is made of an EPDM based rubber compound.

No rules have yet been set out at EU level for the risk assessment and use of rubber. Rubber is not regulated by (EC) 10/2011. Therefore their use should remain subject to national law.



## Netherlands - Dutch Commodities Act "Regeling Verpakkingen- en Gebruiksartikelen (Warenwet)"

According to calculation, described in the Dutch Commodities Act "Regeling Verpakkingen- en Gebruiksartikelen (Warenwet)" chapter 3 – Rubber, the gasket is classified in the Category III:

 Category III comprising rubber products have a R-total < 0.001 and therefore the migration</li> of components is negligible

Based on regulation 328583-117560-VGP (14-03-2014) article 3, first subsection, sub a, and 6a, of the "warenwetbesluit verpakkingen en gebruiksartikelen" the regulation does not apply for packaging or consumables lawfully produced or marketed in another Member State of the European Union.

one type of EPDM gasket is produced in Germany:

## Germany - BFR (Bundesinstitut für Risikobewertung)

The EPDM based rubber compound 2261 meet the requirements of 4th category of the XXIst recommendation of the BFR (Bundesinstitut für Risikobewertung, former BGVV / Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin, former BGA / Bundesgesundheitsamt). Status: 01.03.2011

The category 4 regulates the requirements for rubber articles intended for use in contact with food for a short time or a small contact area.

One type of EPDM gasket is produced in France and meets the requirements of: Positive list of French regulation "Arrêté du 9 novembre 1994, modifié par les arrêtés du 9 août 2005 et du 19 décembre 2006".

#### 5f. Not intentionally added substances

CurTec does not systematically perform specific tests for non-intentionally added substances. We take into account risk assessments carried out by our suppliers on the used raw materials, and handle and process the raw materials as directed by their suppliers, and any known limitation is communicated hereby. No substances to declare.

## 5g. Overall migration

The overall migration results were found to be in compliance with the restriction for the overall migration limit (< 10 mg/dm2) as defined in Commission Regulation (EC) 10/2011 for the food contact materials. For description of final use see paragraph 8.

## 5h. Organoleptic properties

CurTec is a manufacturer of packaging material for a wide range of purposes. This declaration is restricted to the packaging material as it leaves the production facility. Packaging material has been manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could bring about a deterioration in the organoleptic characteristics thereof.



## 6. EU Regulatory status - Used substances

## 6a. Concerning the drum

FCM No.	EEC Ref.No.	CAS No.	Substance name	Limitation mg/kg
356	18820	0000592-41-6	1-Hexene	3

#### *Group restrictions*

There are no group restrictions for used polymers.

## 6b. Concerning the lid

FCM No.	EEC Ref.No.	CAS No.	Substance name	Limitation mg/kg
716	60800	0065447-77-0	1-(2-hydroxyethyl)-4-hydroxy- 2,2,6,6-tetramethyl piperidine- succinic acid, dimethyl ester, copolymer	30
740	81200	0071878-19-8	poly[6-[(1,1,3,3- tetramethylbutyl)amino]-1,3,5- triazine-2,4-diyl]-[(2,2,6,6- tetramethyl-4-piperidyl)-imino] hexamethylene[(2,2,6,6- tetramethyl-4-piperidyl) imino]	3

## **Group restrictions**

There are no group restrictions for used polymers.

Version: 2.7

## 6c. Substances listed in Annex II(1), metals

FCM No.	EEC Ref.No.	CAS No.	Substance name	Max.concentration
		7440-66-6	Zinc	unknown
		7429-90-5	Aluminium	unknown

'Unknown' means the substance is mentioned in the declaration of the material supplier without a specific amount.

Used polymers do not contain substances inn amounts above the SML described in Annex II.

6d. PAAs (Primary Aromatic Amines) covered by Annex II (2) to the Plastics Regulation Total opening drums do not contain intentionally added PAAs.

## 6e. Specific migration

The specific migration results of the restrictions of substances mentioned in points a), b), c), and d) were found to be in compliance with the Commission Regulation (EC) 10/2011 for food contact. The specific migration results are derived from migration modeling or migration testing (based on worst case scenarios).



#### 7. EU Regulatory status - Presence of dual use additives

Identity of substance as listed in the European legislation on additives or flavourings, (Regulation (EC) 1333/2008, Regulation (EC) 1334/2008) (Substance name and E-number or FL-number)

FCM No.	EEC Ref.No.	CAS No.	Substance name	Max. concentration
9	30610,	001592-23-0	E470a Calcium stereate	Unknown
	89040			

<sup>&#</sup>x27;Unknown' means the substance is mentioned in the declaration of the material supplier without a specific amount.

#### 8. EU Regulatory status - Final use of Total opening drums

## 8a. Total opening drums are designed to pack all kinds of food.

Total opening drums have not been tested to be used for infant food.

## 8b. Specification of time and temperature of treatment and storage with food

- Any food contact at frozen and refrigerated conditions.
- Any long term storage at room temperature (up to 25°C) or below
- Heating and/or hot fill up to 70°C for up to 2 hours and cool down <50°C within 60 minutes or < 30°C within 150 minutes
- Heating and/or hot fill up to 100°C for up to 15 minutes and cool down <50°C within 60 minutes or < 30°C within 150 minutes

#### 8c. Repeated use

Product is suitable for repeated use

Version: 2.7

It should be noted that by reusing the packaging the influence on smell, taste and other properties may be different in comparison with a new packaging. It is the responsibility of the user, reusing the packaging, to ensure that the reusage of the article is safe.

## 9. EU Regulatory status - Functional barrier

Total opening drums do not contain plastic layers behind a functional barrier.



#### 10. US Regulatory status - FDA

The used polymers are in compliance with Title 21 Code of Federal Regulations (CFR, 2011 Edition), section 177.1520 (Olefin polymers).

This material may be used under conditions B-H as described in Table 2 of the Code of Federal Regulations (CFR), issued by the Food and Drug Administration (FDA), Title 21, paragraph 176.170 (c) only in contact with types of food I, II, IV-B, VI-A and VII-A, as described in table 1 of CFR, Title 21, paragraph 176.170 (c).

6945 is excluded from the general statement above. For some of the used materials the finished articles are to have a volume of at least 18,9 litres (5 gallons) to comply for fatty foods. The volume of 6945 is smaller than 18,9 litres and therefore not compliant for fatty foods. In case this is problematic, please contact the inside sales department.

## Table 2 - Conditions of use

- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg. F.
- D. Hot filled or pasteurized below 150°F
- E. Room temperature filled and stored (no thermal treatment in the container)
- F. Refrigerated storage (no thermal treatment in the container)
- G. Frozen storage (no thermal treatment in the container)
- H. Frozen or refrigerated storage: ready-prepared foods intended to be reheated in container at time of use.

## Sealing gasket

The EPDM sealing gaskets are conform to §177.2600 CFR/FDA

## 11. Disclaimer

CurTec is a manufacturer of packaging material for a wide range of purposes. This declaration is restricted to the packaging material as it leaves the production facility.

CurTec has neither control over final end use of the product nor over processing conditions. It is therefore the responsibility of the end user to check compliance with the relevant regulations and to validate material performance in the end application through proper end use testing.

The information included in this document is based on the present state of our knowledge, based on the information CurTec received in the declarations of its suppliers. This declaration is valid from the stated issue date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. It will be renewed in all cases where the previous conformity is no longer ensured. In case CurTec initiates a major product change this will be communicated, in case of changes in legislations the document will be updated without a specific notification. We advise to check the issue date of this declaration on a regular basis.



Version: 2.7