

Food contact- Annex colorants

046 – combination of White 004 and Red 402

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

This annex is a child document of the declaration of compliance with respect to the colorants / master batches. Therefor only essential paragraphs are summarized.
Information in this annex is to be used in combination with a declaration of compliance for food contact for specific product category.

4. Issue date

17 April 2015

5. EU regulatory status

5c. Inks, coatings, adhesives and colorants

Master batches are produced in conformity to Framework Regulation EC 1935/2004 and Commission Regulation EC 10/2011. All monomers and additives fulfil the requirements for food contact.

Pigments are not subject to Commission Regulation EC 10/2011. Used pigments are in compliance with:

French Positive List

6. EU Regulatory status - Used substances

The possible used colorants:

- 004 11898-I manufactured by Ampacet
- 004 MLL-17340-WX manufactured by Addvanze
- 402 ERN33960 manufactured by Schulman
- 402 MLL-10339-RM manufactured by Addvanze

Used substances

FCM No.	EEC Ref.No.	CAS No.	Substance name	Limitation mg/kg
19	39090	----	Ethanol, 2,2-iminobis-, N-C12-18-alkyl derivs, expressed as tertiary amine	1,2(T)
106	24550, 89040	0000057-11-4	Stearic acid, expressed as zinc	25
248	19540, 64800	0000110-16-7	maleic acid, expressed as maleic acid	30(T)
433	68320	0002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)p	6

Group restrictions

There is a group restriction for substance with FCM no. 19 in combination with FCM no. 20 and for substance FCM no. 248 in combination with FCM no. 234.

Substances listed in Annex II(1), metals

The master batch does not contain Substances listed in Annex II

Specific migration

The specific migration results of the restrictions of substances mentioned in paragraph 6 were found to be in compliance with the Commission Regulation (EC) 10/2011 for food contact. The specific migration results are derived from migration modelling or migration testing (based on worst case scenarios; worst case polymer with worst case masterbatch).

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, 89040	001592-23-0	E470a Calcium stearate	0,0009
21	42500	000471-34-1	E170 carbonic acid, salts	0,3023
106	24550, 89040	----	E470 Calcium salt	nias
504	86240	007631-86-9	E551 silicon dioxide	0,0053
610	93440	013463-67-7	E171, TiO ₂	0,9

‘nias’ : Non-intentionally added substances are either impurities in the substances used or reaction intermediates formed during the polymerisation process or decomposition or reaction products which can occur in the final product.

10. US Regulatory status - FDA

The used master batch is in compliance with Title 21 Code of Federal Regulations, sections below are specified in declarations from our suppliers;

- Section 178.2010 (Antioxidants and Stabilizers)
- Section 178.3297 (Colorants for polymers)

11. Disclaimer

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DECLARATION OF COMPLIANCE

Food contact

Wide neck drums

1. DoC issued by

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3. Product identity

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

<i>Drum</i>	<i>Capacity</i>	<i>Lid</i>
7003	3,6 litre	7006
7004	3,6 litre	7006
7006	6 litre	7006
7010	10 litre	7026
7011	10 litre	7026
7015	15 litre	7026
7020	20 litre	7026
7026	26 litre	7026
7042	42 litre	7055
7055	55 litre	7055
7068	68 litre	7055

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

4. Issue date

31 March 2015, based on specification of used materials dated 31 March 2015

5. EU regulatory status – Wide neck drums

EC regulation 1935/2004

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

GMP

Wide neck 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) 2015/174).

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 its 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 a NR/SBR or 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 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.

- NR/SBR gasket and one type of EPDM gasket are produced in Germany:

Germany - BFR (Bundesinstitut für Risikobewertung)

The NR/SBR based rubber compound 2061 and the EPDM based rubber compound 2261 meet the requirements of 4th category of the XX1st 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.

The NR/SBR based rubber compound 2061 contains chemicals which can form nitrosamines during the cross-linking process. The resulting profiles may therefore release ppb-amounts of nitrosamines.

If it is intended to utilize compound 2061 as sealing gasket for packaging sensitive goods, such as foodstuffs or pharmaceuticals, a risk assessment should be made in order to avoid any adverse effects on the integrity of the packaged product

- 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

A risk assessment for non-intentionally added substances has not been performed and should therefore be evaluated by the downstream user.

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. This declaration does not cover any negative influence on the organoleptic properties of the packaged food.

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
500	38560	0007128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	0,6

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
106	24550, 89040	0000057-11-4	Stearic acid, expressed as zinc	25
356	18820	0000592-41-6	1-Hexene	3
368	93280	0000693-36-7	thiodipropionic acid, dioctadecyl ester	5
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.

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

FCM No.	EEC Ref.No.	CAS No.	Substance name	Max.concentration
-	-	----	Zinc	unknown

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

6d. PAAs (Primary Aromatic Amines) covered by Annex II (2) to the Plastics Regulation

Wide neck 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, 89040	001592-23-0	E470a Calcium stearate	Unknown

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

8. EU Regulatory status - Final use of Wide neck drums

8a. Wide neck drums are designed to pack all kinds of food.

Wide neck 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 up to 70°C for up to 2 hours
- Heating up to 100°C for up to 15 minutes

8c. Repeated use

- Product is suitable for repeated use

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 reuse of the article is safe.

9. EU Regulatory status - Functional barrier

Wide neck 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).

We declare that the used polymers are allowed to get in contact with all types of food (types “I to IX”) as described in Table 1 of § 176.170(c) for conditions of use “B” to “H” described in Table 2 of § 176.170(c) of this chapter.

7003, 7004, 7006, 7010, 7011, 7015 are 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 these drums is smaller than 18,9 litres and therefore not compliant for fatty foods. In case the non-compliance for fatty food 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
- The NR/SBR sealing gasket meets almost completely the requirements of §177.2600 CFR/FDA. The extraction test regarding the suitability for fatty foods exceeds however the specification limits
- The NR/SBR sealing gasket contains chemicals which can form nitrosamines during the cross-linking process. The resulting profiles may therefore release ppb-amounts of nitrosamines.
If it is intended to utilize the NR/SBR sealing gasket for packaging sensitive goods, such as foodstuffs or pharmaceuticals, a risk assessment should be made in order to avoid any adverse effects on the integrity of the packaged product.

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Pigments are not subject to Commission Regulation EC 10/2011. Used pigments are in compliance with:

French Positive List

6. EU Regulatory status - Used substances

The possible used colorants:

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- 004 MLL-17340-WX manufactured by Addvanze
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Used substances

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Group restrictions

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Substances listed in Annex II(1), metals

The master batch does not contain Substances listed in Annex II

Specific migration

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Specification of used materials

Wide Neck Drums and Total Opening Drums

Specification issued by

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Wide Neck Drums and Total Opening Drums

Each drum consists of a drum and a lid. The lid contains a sealing gasket.

Drum

ExxonMobil HYA600
Ineos Rigidex HD5502S
Sabic HDPE B5933
Sabic HDPE B5429
Braskem HS5502
Chevron Phillips Marlex HHM 5502BN

Lid

ExxonMobil HMA035
Ineos Rigidex HD6070UA
Sabic HDPE M80064SE
Sabic HDPE M80064S

Sealing gasket

EPDM – Compound 2261 light: manufactured by Leeser
EPDM – MEL-CEL-FDA: manufactured by Francem
NR/SBR – Compound 2061 light: manufactured by Leeser

Issue date:

31 March 2015