

1105-xxxx Disposal kegs, wide-mouth containers

We hereby confirm that the above-mentioned product, consist of a drum and a lid. The screw lid contains a mounted sponge rubber sealing gasket.

EU regulatory status – Wide mouth drums

EC regulation 1935/2004

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

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.

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.

EU Regulatory status - Used substances

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

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

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).

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

Wide mouth drums are designed to pack all kinds of food.

Wide mouth drums have not been tested to be used for infant food.

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

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.

EU Regulatory status - Functional barrier

Wide mouth drums do not contain plastic layers behind a functional barrier.

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.

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.

Our supplier 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 declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 2284-08.

31. March 2015

A handwritten signature in blue ink, appearing to read "M. Saint-Denis".

Bürkle GmbH, Bad Bellingen,
Martin Saint-Denis, Managing Director

