



Desmopan® 9370A GMP 000000

General

Desmopan® 9370A GMP 000000 may be used for the manufacture of articles intended for food contact as outlined below. Desmopan® 9370A GMP 000000 belongs to the group of thermoplastic polyurethanes.

Europe

Regulation (EC) 1935/2004

This statement has the purpose of a declaration of compliance as required by Regulation (EC) 1935/2004.

Desmopan® 9370A GMP 000000 is manufactured applying rules on Good Manufacturing Practice (GMP) which are considered appropriate for plastic raw materials as required by Regulations (EC) 1935/2004 and (EC) 2023/2006. This includes the use of procedures to cover traceability from the incoming starting materials to the outgoing food contact material.

Commission Regulation (EU) 10/2011

Desmopan® 9370A GMP 000000 is manufactured only with monomers and additives that are authorized under the Commission Regulation (EU) No. 10/2011 of 14 January 2011 on “plastic materials and articles intended to come into contact with food”. All monomers and additives used for the manufacture of Desmopan® 9370A GMP 000000 are listed in Annex I of the Commission Regulation (EU) No. 10/2011.

Specific limits

The table below provides information on certain restrictions which must be observed according to Commission Regulation (EU) No. 10/2011:

CAS number	Name	Restrictions (QM=max. permitted quantity of residual in plastic ; SML=specific migration limit in food or simulant)
000110-63-4	1,4-Butanediol	SML = 5 mg/kg
000109-99-9	Tetrahydrofuran	SML = 0.6 mg/kg
000101-68-8	Diphenylmethane-4,4'-diisocyanate	QM = 1 mg/kg (expressed as NCO)
000075-56-9	Propylene oxide	QM = 1 mg/kg
002082-79-3	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, octadecyl ester	SML = 6 mg/kg
00128-37-0	2,6-Di-tert-butyl-p-cresol	SML = 3mg/kg

This information and our technical advice - whether verbal, in writing or by ways of trial - are given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved.

The information is provided by Covestro Deutschland AG without assumption of any liability. If any of the above mentioned regulations change after the date of declaration, this declaration is no longer valid. Covestro Deutschland AG will strive to keep this information up-to-date.

Our advice does not release you from the obligation to verify the information provided – especially that contained in our safety data and technical information sheets –, to check for updates of any information provided by us and to test our products as to their suitability for the intended processes and uses. The application, use and processing of our products and the products manufactured by you on the basis of our technical advice are beyond our control and, therefore, entirely your own responsibility.

Our products are sold in accordance with the current version of our General Conditions of Sale and Delivery.



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Assessment:

The above mentioned limits have been met in exemplary investigations by virgin material representative of the composition of Desmopan® 9370A GMP 000000.

Risk assessment has been performed according to Article 19 regulation (EU) 10/2011 for the following use conditions: food simulant E (Tenax®) for 30 min at 40°C and evaluated for a surface/volume ratio of 6 dm²/kg.

It is the responsibility of the user of our products, who manufactures materials or articles intended for food contact or brings them into contact with food, to assure their compliance with limits and other provisions set by the applicable regulations.

Germany

BfR Recommendations on Food Contact Materials

(Bundesinstitut für Risikobewertung/Federal Institute for Risk Assessment)

With respect to its additives and further constituents, Desmopan® 9370A GMP 000000 complies with the requirements of Recommendation XXXIX "Commodities Based on Polyurethanes", issued by the Federal Institute for Risk Assessment (BfR), status: 2012-01-01.

Consumer Goods Ordinance

(Bedarfsgegenständeverordnung)

With respect to its monomer and additive composition, Desmopan® 9370A GMP 000000 complies with the requirements of the German Consumer Goods Ordinance (up to the 20th amendment, published in Bundesgesetzblatt 2011 part I no. 6, 2011-02-07).

USA

Desmopan® 9370A GMP 000000 is in chemical compliance with FDA's Regulation in 21 CFR § 177.1680 (Polyurethane resins). Please note that § 177.1680 allows the contact of polyurethane surfaces only with dry and solid food, which is free of oil and fat on its surface.

Desmopan® 9370A GMP 000000 may be used in food-contact applications in compliance with FDA's Regulation in 21 CFR § 177.2600 (Rubber articles intended for repeated use) as a component of rubber articles that otherwise comply with § 177.2600, subject to the limitations of this regulation and any other applicable regulations.

BSE Statement (Bovine Spongiform Encephalitis)

Desmopan® 9370A GMP 000000 contains a fatty acid amide as a mold release agent. Fatty acids may have been produced from animal or vegetable fat and oil. The producers of the fatty acid amide have submitted us a declaration that it has been produced under conditions in compliance with EU Regulation (EC) 142/2011, and consequently, EMA/410/01 Rev. 3.



Statement on Food Contact Use

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All other chemicals used for the production of Desmopan® 9370A GMP 000000 are of petro-chemical / synthetic origin.

Therefore we are convinced that there is no risk of contamination with BSE germs.

Comment

The entire confirmation only applies to the granules as supplied by Covestro Deutschland AG.

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