



Desmopan® 9852D GMP 000000

General

Desmopan® 9852D GMP 000000 may be used for the manufacture of articles intended for food contact as outlined below. Desmopan® 9852D GMP 000000 belongs to the group of polyurethane / ABS blends.

Europe**Regulation (EC) 1935/2004**

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

Desmopan® 9852D 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® 9852D 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® 9852D 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)
000106-99-0	Butadiene	QM = 1 mg/kg (in final product)
000128-37-0	2,6-Di-tert-butyl-p-cresol	SML = 3 mg/kg
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
000107-13-1	Acrylonitrile	SML = ND

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 If any of the above mentioned regulations change after the date of declaration, this declaration is no longer valid.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:

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.

USA

Desmopan® 9852D GMP 000000 may be used in food-contact applications in compliance with 21 CFR 177.1680 (Polyurethane resins) and 181.32 (Acrylonitrile copolymers and resins) as a component of articles intended for repeated use contact with bulk quantities of dry food.

Desmopan® 9852D GMP 000000 may be used in food-contact applications in compliance with 21 CFR 177.2600 (Rubber articles intended for repeated use) and 181.32 (Acrylonitrile copolymers and resins) as a component of articles intended for repeated use contact with all food types.

The use of Desmopan® 9852D GMP 000000 is subject to the limitations of these regulations and any other applicable regulations.

BSE Statement (Bovine Spongiform Encephalitis)

Desmopan® 9852D GMP 000000 contains derivatives of fatty acids as a monomer and as a mold release agent. Fatty acids may have been produced from animal or vegetable fat and oil. The producers of the derivatives of fatty acids have submitted us a declaration that they have been produced under conditions in compliance with the Commission Regulation (EU) No. 142/2011, and consequently, Note for Guidance EMA/410/01 Rev. 3.

All other chemicals used for the production of Desmopan® 9852D GMP 000000 are of petro-chemical / synthetic origin.

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



Statement on Food Contact Use

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Comment

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

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