

Regulatory Affairs Product Information Data Sheet (RAPIDS)

Lupolen 5021 DX

- **FOOD APPROVALS**

EU (A; B; DK; SE; F; D; GR; IRL; I; L; N; P; E; S; CH; UK; NL; Czech Republic)

For all types of food.

There is a SML established for a monomer in this grade.

Compliance as above refers to Directive 2002/72 and to National Regulations for additives not yet included in Directive 2002/72.

The final item producer is responsible for evaluation of global migration at the real time/temperature conditions

United States of America

The base resin in *Lupolen 5021 DX* meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (3) (i) (a) (1) and (c). According to information received from all of our suppliers, all other ingredients used in *Lupolen 5021 DX* meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b). *Lupolen 5021 DX* meets the FDA criteria in 21 CFR 177.1520 for food contact applications, listed under conditions of use **A** through **H** in 21 CFR 176.170 (c), Table 2. *Lupolen 5021 DX* can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1.

- **Chemical Inventories**

All ingredients in *Lupolen 5021 DX* are in compliance with the following chemical inventories:

United States: Toxic Substances Control Act Inventory (TSCA)

Canada: Domestic Substances List (DSL) – Non Domestic Substances List (NSDL)

Europe: European Inventory of Existing Commercial Chemical Substances (EINECS)

European List of Notified Chemical Substances (ELINCS)

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (ECL)

Japan : Japanese Existing and New Chemical Substances (ENCS)

Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)

Lupolen 5021 DX has no special requirements under US TSCA (e.g. consent orders, test rules, 12 (b) requirements, etc.).

- **European Pharmacopeia (EP)**

The composition of **Lupolen 5021 DX** is in compliance with monographs 3.1.3 and 3.1.5 4th Ed. of European Pharmacopoeia.

- **Toys (CEN Standard EN71.3)**

Lupolen 5021 DX is in compliance with CEN Standard EN71.3.

- **Ozone Depleting Substances**

Ozone Depleting Substances are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **OESTROGEN MIMICS**

Substances actually identified as oestrogen mimics are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **Phthalates in toys**

The phthalates ex art.1 of Decision 1999/815/EC are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **Phthalates in polymers and rubbers**

The phthalates as for Decree of Italian Ministry of Health n°538 of 17/12/1999 are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **Latex**

"Natural rubber latex", "synthetic latex" or "natural rubber" are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **US Pharmacopeia (USP)**

Lupolen 5021 DX has not been tested for USP

- **Drug Master File (DMF)**

Information on **Lupolen 5021 DX** is listed in DMF. 15675

- **Heavy metals (Directive 94/62 EEC)**

CADMIUM, CHROMIUM (VI), MERCURY, LEAD are not intentionally added to our grade **Lupolen 5021 DX** and the incidental sum of the concentration in this product does not exceed 100 parts per million by weight.

Lupolen 5021 DX can be recycled according to Directive 94/62 requirements.

- **Coalition of Northeastern Governors (CONEG)**

Cadmium, chromium, lead and mercury are not used in the manufacture of or the formulation of **Lupolen 5021 DX**, therefore it meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

- **SWITZERLAND "VOC-LENKUNGSABGABE"**

Lupolen 5021 DX contains less than 3% VOC's of the Substances positive lists of above Regulations.

- **AROMATIC AMINES**

"AROMATIC AMINES" are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **ASBESTOS**

ASBESTOS is not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **PCB's/PCT's**

"PCB's" / "PCT's" are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **KOSHER**

Lupolen 5021 DX cannot be certified under KOSHER rules.

- **Tin compounds**

"Tin compounds" are not used in the manufacture of or the formulation of **Lupolen 5021 DX**.

- **Composting** (Ref: CEN Standard prEN 13432)

This raw material is not suitable for composting.

- **Energy Recovery** (Ref: CEN Standard prEN 13431)

The calorific gain from this raw material in an energy recovery process is 22MJ/Kg.

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. Because of possible changes in the law and in regulations, we recommend that customers continuing to use our product verify status every six months from this date.

Certified for Basell by:

Patrizia Busi – Regulatory Affairs Manager

[ph: 0039-0532-468653; e-mail: patrizia.busi@basell.com]

(update : 01/ 10 / 2002 - **This certificate shall continue in effect for 6 months from its effective date**)

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