



## Regulatory Affairs Product Information Data Sheet (RAPIDS)

# DOMOLEN<sup>®</sup> 2500H

- **FOOD APPROVALS**

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

Compliance as above refers to Directive 2002/72 up to its last amendment in force, as implemented into the single members States Regulations. Some additives are subjected to a specific migration limit (SML).

**Regulation 1935/2004/EC**

**DOMOLEN<sup>®</sup> 2500H** is a plastic material for which specific measures are adopted as foreseen in article 5 of Regulation 1935/2004/EC. For plastic materials and articles specific measures are adopted through directive 2002/72/EC and amendments.

**United States of America**

The base resin in **DOMOLEN<sup>®</sup> 2500H** meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (1) (i) and (c) (1.1a). According to information received from all of our suppliers, all other ingredients used in **DOMOLEN<sup>®</sup> 2500H** meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b). **DOMOLEN<sup>®</sup> 2500H** meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use **A** through **H** in 21 CFR 176.170 (c), Table 2. **DOMOLEN<sup>®</sup> 2500H** can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1.

- **Chemical Inventories**

All ingredients in **DOMOLEN<sup>®</sup> 2500H** are in compliance with the following chemical inventories:

<u>United States</u>	: Toxic Substances Control Act Inventory (TSCA)
<u>Canada</u>	: Domestic Substances List (DSL) – Non Domestic Substances List (NSDL)
<u>Europe</u>	: European Inventory of Existing Commercial Chemical Substances (EINECS) European List of Notified Chemical Substances (ELINCS)
<u>Australia</u>	: Australian Inventory of Chemical Substances (AICS)
<u>Korea</u>	: Korean Existing Chemicals List (ECL)
<u>Japan</u>	: Japanese Existing and New Chemical Substances (ENCS)

**DOMOLEN<sup>®</sup> 2500H** has no special requirements under US TSCA (e.g. consent orders, test rules, 12 (b) requirements, etc.).

- **European Pharmacopoeia (EP)**

**DOMOLEN<sup>®</sup> 2500H** cannot be certified for E.P.

- **Ozone Depleting Substances**

Ozone Depleting Substances are not used in the manufacture of or the formulation of **DOMOLEN<sup>®</sup> 2500H**.

- **OESTROGEN MIMICS**

Substances actually identified as oestrogen mimics are not used in the manufacture of or the formulation of **DOMOLEN<sup>®</sup> 2500H**.

- **Phthalates in toys and childcare articles (Directive 2005/84/EC)**

**DOMOLEN<sup>®</sup> 2500H** is in full compliance with the European regulations according to guideline 2005/84/EG.

DINP, DODP and DNOP are not intentionally used in the manufacturing process of the **DOMOLEN<sup>®</sup> 2500H**

The amount of DEHP, DBP and BBP doesn't exceed 0,1% in **DOMOLEN<sup>®</sup> 2500H**.



- **US Pharmacopeia (USP)**

**DOMOLEN<sup>®</sup> 2500H** has not been tested for USP.

- **Latex**

"Natural rubber latex", "synthetic latex" or "natural rubber" are not used in the manufacture of or the formulation of **DOMOLEN<sup>®</sup> 2500H**.

- **Drug Master File (DMF)**

The product **DOMOLEN<sup>®</sup> 2500H** is not listed in DMF

- **Packaging and packing waste (Directive 94/62 EEC)**

Compliance as above refers to Directive 94/62 up to its last amendment in force, as implemented into the single members States Regulations.

**DOMOLEN<sup>®</sup> 2500H** can be recycled according to Directive 94/62 requirements.

- **Heavy metals (Directive 2002/53 EEC)**

CADMIUM, CHROMIUM (VI), MERCURY, LEAD are not intentionally added to our grade **DOMOLEN<sup>®</sup> 2500H** and the incidental sum of the concentration in this product does not exceed 100 parts per million by weight.

- **Restrictions on the use of certain hazardous substances in electrical and electronic equipment (Directive 2002/95 EEC)**

**DOMOLEN<sup>®</sup> 2500H** is in full compliance with the European regulations according to guideline 2002/95/EG issued by the European commission January 2003 concerning restrictions on the use of hazardous substances (various heavy metals (lead, mercury, cadmium, and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) in electrical and electronic equipment.

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

Cadmium, chromium, lead and mercury are not used in the manufacture of or the formulation of **DOMOLEN<sup>®</sup> 2500H**, therefore it meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

- **SWITZERLAND "VOC-LENKUNGSABGABE"**

**DOMOLEN<sup>®</sup> 2500H** contains less than 3% VOC's of the Substances positive lists of above Regulations.

- **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 24MJ/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 three years from this date.

---

For further information please contact: [polypropylene@domo.org](mailto:polypropylene@domo.org)