

Regulatory Affairs Product Information Data Sheet (RAPIDS)

Moplen EP348U

- FOOD APPROVALS

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

For all types of food.

One additive in this formulation has a SML

There could be a processing aid for which a SML is established. The SML will not be exceeded even with a 100% migration for a container up to 0,25 mm thick

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/specific migration at the real time/temperature conditions

United States of America

The base resin in **Moplen EP348U** meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (3) (i) and (c). According to information received from all of our suppliers, all other ingredients used in **Moplen EP348U** meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b). **Moplen EP348U** meets the FDA criteria in 21 CFR 177.1520 for food contact applications, listed under conditions of use **C** through **G** in 21 CFR 176.170 (c), Table 2. **Moplen EP348U** can be used in contact with food of types II, III, IV, V, VII-A, IX as listed in 21 CFR 176.170 (c), Table 1.

- Chemical Inventories

All ingredients in **Moplen EP348U** 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)

Philippines: Philippine of Chemicals and Chemical Substances (PICCS)

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Moplen EP348U has no special requirements under US TSCA (e.g. consent orders, test rules, 12 (b) requirements, etc.).

- European Pharmacopoeia (EP)

Moplen EP348U cannot be certified for E.P.

- Toys (CEN Standard EN71.3)

Moplen EP348U 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 **Moplen EP348U**.

- OESTROGEN MIMICS

Substances actually identified as oestrogen mimics are not used in the manufacture of or the formulation of **Moplen EP348U**.

- Phthalates in toys

The phthalates ex art.1 of Decision 1999/815/EC are not used in the manufacture of or the formulation of **Moplen Moplen EP348U**

- 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 **Moplen EP348U**.

- Latex

"Natural rubber latex", "synthetic latex" or "natural rubber" are not used in the manufacture of or the formulation of **Moplen EP348U**

- Drug Master File (DMF)

The product **Moplen EP348U** is not listed in our DMF.

- US Pharmacopeia (USP)

Moplen EP348U cannot be certified for USP

- Heavy metals (Directive 94/62 EEC)

CADMIUM, CHROMIUM (VI), MERCURY, LEAD are not intentionally added to our grade **Moplen EP348U** and the incidental sum of the concentration in this product does not exceed 100 parts per million by weight.

Moplen EP348U 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 **Moplen EP348U**, therefore it meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

- SWITZERLAND "VOC-LENKUNGSABGABE"

Moplen EP348U contains less than 3% VOC's of the Substances in the positive lists of the above Regulations.

- **AROMATIC AMINES**

"AROMATIC AMINES" are not used in the manufacture of or the formulation of **Moplen EP348U**.

- **ASBESTOS**

ASBESTOS is not used in the manufacture of or the formulation of **Moplen EP348U**.

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

"PCB's" / "PCT's" are not used in the manufacture of or the formulation of **Moplen EP348U**.

- **KOSHER**

Moplen EP348U cannot be certified under KOSHER rules.

- **Tin compounds**

"Tin compounds" are not used in the manufacture of or the formulation of **Moplen EP348U**.

- **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 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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