



## CERTIFICATE

### ARMOSLIP CP

when leaving the factory, has the following compliance status with the below mentioned regulations on food-contact plastics, on materials intended to carry drinking water and on plastics intended to contact pharmaceuticals.

#### 1 INDIRECT FOOD CONTACT

##### 1.1 Europe (EC-Countries)

Oleamide (PM/REF No 68960) is listed in annex III of directive 96/11/EC, "list of additives inserted in annex III of directive 90/128/EEC". This means that **Armoslip CP** is cleared for use in the manufacture of plastic materials and articles intended to come into contact with foodstuffs, **without restrictions**. The final material should be in compliance with the relevant EC directives (89/109/EEC, 90/128/EEC, 82/711/EEC and amendments).

When this certificate has been issued the directive 96/11/EC has been adopted into national law in the following EC countries (for details see below): Austria, Belgium, Denmark, Finland, France, Germany, Italy, the Netherlands, Portugal, Spain, Sweden and UK.

##### 1.1.1 Austria

Directive 96/11/EC adopted by Änderung der Kunststoffverordnung Nr. 262, 16.9.1997, BGBl Nr. 11: **No restrictions.**

##### 1.1.2 Belgium

Directive 96/11/EC adopted by Royal Decree of 24 November 1997, Moniteur Belge, 13.2.1998: **No restrictions.**

##### 1.1.3 Denmark

Directive 96/11/EC adopted by Sundhedsministeriets Bekendtgørelse nr 1064, 4 December 1997: **No restrictions.**

##### 1.1.4 Finland

Directive 96/11/EC adopted by Decree No. 1071/96: **No restrictions.**

##### 1.1.5 France

Directive 96/11/EC adopted by Arrêté du 30 Septembre 1997, Journal Officiel Français 19.10.1997: **No restrictions**



### 1.1.6 Germany

Cleared in the following BgVV-Empfehlungen (recommendations):

III. Polyethylen, as a slip, antiblocking or antistatic agent, pH-regulator etc. for processing polyethylene polymer into finished articles, not to exceed 0.2 % w/w. Oleamide may contain at maximum 10 % linoleic acid.

V. Polystyrol, as a slip and/or release agent, at maximum 0.2 % w/w

VI. Styrol-Misch und -Pfropfpolymerisate (styrene copolymers), as a slip and/or release agent, at maximum 0.2 % w/w

VII. Polynorpropylen, as a slip, antiblocking or antistatic agent, pH-regulator etc. for processing polyethylene polymer into finished articles, not to exceed 0.2%. Oleamide may contain at maximum 10 % linoleic acid.

XXV. Hartparaffine, mikrokristalline Wachse und deren Mischungen mit Wachsen, Harzen und Kunststoffen (solid paraffins, microcrystalline waxes), as an aid, not to exceed 2.0 % w/w.

XXXV. Mischpolymerisate aus Ethylen, Propylen, Butylen, Vinylestern und ungesättigten aliphatischen Säuren sowie deren Salzen und Estern (copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids and their salts and esters),

- a) as an additive for processing of non cross-linked copolymers into finished articles, not to exceed 0.3 % w/w; oleamide may contain at maximum 10 % linoleic acid,
- b) as an additive for processing ionic cross-linked copolymers into finished articles, not to exceed 0.2 % w/w.

Listed in the incomplete list of additives „Bekanntmachung des unvollständigen Verzeichnisses von Additiven, die bei der Herstellung von Lebensmittelbedarfsgegenständen aus Kunststoff verwendet werden dürfen“ published in the Bundesanzeiger Nr. 128, July 15, 1997 p. 8673 and adopting directive 90/128/EEC and its amendments into German law: **No restrictions.**

### 1.1.7 Italy

Directive 96/11/EC adopted by Decreto Ministeriale di 6.2.1997, no. 91, Gazzetta Ufficiale, 3.4.1997: **No restrictions.**

### 1.1.8 Spain

Directive 96/11/EC adopted by Real Decreto 1042/97 of 27.6.1997 (BOE no. 173 and BOE no 238), no. 91, Gazzetta Ufficiale, 3.4.1997: **No restrictions.**

Listed in Resolucion de 4 noviembre de 1982 as an additive without restrictions

### 1.1.9 The Netherlands

Directive 96/11/EC adopted by Implementatie richtlijn 96/11/EG (verpakkingen en Gebruiksartikelen): **No restrictions.**

### 1.1.10 UK

Directive 96/11/EC adopted by S.I. 1996/No. 2617: **No restrictions.**

## 1.2 Europe (non-EC countries)

### 1.2.1 Czechia

Cleared in Hygienic Regulation Volume 42/1978 for the use in PE under „amides of higher fatty acids including 16 to 22 C-atoms in an acid molecule, at a max. of 0.2%.

### 1.2.2 Switzerland

Cleared in the Verordnung über Materialien und Gegenstände aus Kunststoff (Kunststoffverordnung), amended 30.01.1998, in list 2 (additives) as oleamide without restrictions.



### 1.3 Australia

Listed in Australian Standard AS 2070.8, 1992 as oleamide and cleared for use as an additive

- in PE, the total content of additives with the same restriction is limited to max. 0.2%.
- in PP in quantities of max. 0.5%,
- in PVC in quantities of max. 1%,
- in acrylonitrile in quantities of max. 0.2%,
- in PVDC in quantities of max. 0.5%.

### 1.4 Canada

**Armoslip CP** is approved by the Bureau of Chemical Safety (under Health Canada) for use as a slip agent, at a max. of 0.2% by weight, in LDPE and LLDPE food packaging films.

### 1.5 India

Listed in:

- Indian Standard IS 10141-1982 as lubricant for LDPE under „amides of fatty acids, saturated or not“, in quantities of max. 0.2%.
- Indian Standard IS 10141-1982 as lubricant for HDPE under „amides of erucic, linoleic, myristic, oleic, palmitic, pelargonic and stearic acids“, in quantities of max. 0.2%.
- Indian Standard IS 10909-1984 as lubricant for PP under „amides of erucic, linoleic, myristic, oleic, palmitic, pelargonic and stearic acids“, in quantities of max. 0.2%.
- Indian Standard IS 10148-1982 as lubricant for PVC and its copolymers „amides of linoleic, myristic, oleic, palmitic, ricinoleic and stearic acids“, in quantities of max. 0.3%.

Not listed in Indian Standard IS 11705-1986 (ethylene acrylic acid copolymers), Indian Standard IS 11435-1985 (ionomer resins).

Unknown status in Indian Standard IS 10148-1982 (styrene polymers).

### 1.6 Japan

Listed in the Self-restrictive Requirements on Food-Contacting Articles Made of Polyolefins and Certain Polymers issued by the Japanese Hygienic Olefin and Styrene Association (JHOSPA), 1996 as

- higher fatty acid (C8-C22) amides: Cleared as slip agent in PE in quantities of max. 1.0% (containers); 2.0% (utensils),
- oleylamide: Cleared as slip agent in PP in quantities of max. 0.4%,
- higher fatty acid (C8-C22) amides: Cleared as slip agent in polymethyl pentenes in quantities of max. 0.2% (containers); 2.0% (utensils),
- higher fatty acid (C8-C22) amides: Cleared as slip agent in polybut-1-ene, in polyamide resins and in polyvinyl alcohol in quantities of max. 0.1% (containers); 2.0% (utensils),
- higher fatty acid (C8-C22) amides: Cleared as slip agent in butadiene resins in quantities of max. 0.5% (containers); 2.0% (utensils),
- oleylamide: Cleared as slip agent in PS, SAN, styrene methacrylic resins and ABS in quantities of max. 0.02%,
- higher fatty acid (C8-C22) amides: Cleared as slip agent in fluorine resins in quantities of max. 1.0% (containers); 2.0% (utensils),
- higher fatty acid (C8-C22) amides: Cleared as slip agent in polyacetal resins in quantities of max. 2.0% (utensils).

Listed in PVC for Food Contact Applications, a code of PVC for safety in use issued by the Japanese Hygienic PVC Association, 9th revision, March 1989, as higher fatty acid (C8-C22) amides derived from animal/vegetable fat and oil, or the hydrogenated products of such acids; quality restrictions: melting point > 65 °C; acid value < 10, iodine value 50 - 90, volatile matter < 0.5%, heavy metals < 20 ppm, arsenic < 2 ppm. Restriction for sealing gaskets: maximum quantities not to exceed 5%.



## 1.7 USA

Oleamide (oleic acid amide) is cleared in 21 CFR (FDA) under

- § 175.105 (adhesives),
- § 175.300 (resinous and polymeric coatings) (b)(3)(xxv) for the use as a release agent,
- § 175.320 (resinous and polymeric coatings for polyethylene films) (b)(3)(iii) as „amides (unsubstituted) of fatty acids from vegetable or animal oils“ for the use as an adjuvant
- § 175.380 (xylene formaldehyde resins condensed with 4,4-isopropylidenediphenol epichlorohydrin epoxy resins),
- § 175.390 (zinc-silicon dioxide matrix resins),
- § 176.170 (components of paper and paper board in contact with aqueous and fatty foods),
- § 177.1210 (closures with sealing gaskets for food containers)
- § 177.1350 (ethylene-vinyl acetate copolymers)
- § 177.1520 (olefin polymers) (b), referring to an adjuvant permitted by applicable regulations in §§ 170 through 189,
- § 178.3910 (surface lubricants used in the manufacture of metallic articles) in the drawing, stamping or forming of metallic articles from rolled foil or sheet stock by further processing provided that the total residue lubricant does not exceed 0.2 mg per square inch of food-contact surface,
- § 179.45 (packaging materials for use during irradiation of prepackaged foods) (d)(2)(i) as an adjuvant, in levels not to exceed 1% w/w of the polymer,
- § 181.28 (release agents) as specific prior-sanctioned food ingredient under substances employed in the manufacture of food-packaging materials as a release agent, when migrating from food-packaging material.

## 2 MATERIALS INTENDED TO CARRY DRINKING WATER

### 2.1 Germany

Cleared in the following KTW-Empfehlungen (recommendations):

- Part 1.3.2 Polyethylen, for the use as an additive in the manufacturing of the final material in quantities of total max. 0.2% (as single additive or in combination with other listed amides; oleamide may contain at maximum 3.0 % linoleic acid),
- Part 1.3.3 Polypropylen, for the use as an additive in the manufacturing of the final material in quantities of total max. 0.2% (as single additive or in combination with other listed amides; oleamide may contain at maximum 5.0 % linoleic acid),
- Part 1.3.13 Gummi aus Natur- und Synthesekautschuk, listed as fatty acid amides C14-C20, as a vulcanization activator without restrictions.

### 2.2 India

Indian Standards see information listed under indirect food contact.

## 3 PHARMACEUTICAL USE AND MEDICAL APPLICATIONS

### 3.1 European Pharmacopoeia (3rd. ed. 1997)

Cleared as an additive (listed as alkenamides) used for the manufacture of polyolefin containers.  
Restrictions: maximum allowable content: 0.5% - may be used only for containers for preparations for oral use.

### 3.2 India

Indian Standards see information listed under indirect food contact.



#### 4 HEAVY METAL CONTENT

Sb	As	Fe	Ba	Cd	Cr	Pb	Hg	Se
<0.5*)	<2*)	<0.5*)	<0.1*)	<0.1*)	<0.5*)	<1*)	<0.5*)	<2*)

\*) The product does not contain detectable amounts. The figures given are the corresponding detection limits (in mg/kg).

#### 5 LIST OF ABBREVIATIONS

EC: European Commission

KTW: "Kunststoff-Trinkwasser-Empfehlungen"

PM/Ref: Packaging Materials Reference Number

QM: Quantitative Maximum (maximum amount of a substance permissible in a food contact material such that the SML cannot be exceeded)

SML: Specific Migration Limit

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