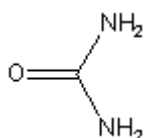


**PRODUCT CODE: 191754****Urea crystalline (USP, BP, Ph. Eur.) pharma grade**CH₄N₂ONH₂CONH₂

M.= 60,06 CAS [57-13-6] EINECS 200-315-5

TARIC 3102 10 10 00

SYNONYMS: Carbamide, Carbonyldiamide**PHYSICAL DATA:** crystalline powder, White, in water at 20C Thermal decom. above 135 C · D 20/4 1,34 · M.P.: 135 C · pH_{9,2} - 9,5 ·**BIBLIOGRAPHY:** Merck Index **13**, 9.935 Sax **USS000** · Safety **2**, **3578 A** · Rmp **8**, **1629** · Beilstein **3**, **42 I**, **19 II**, **35 III**, **80 IV**, **94** · BRN 635724 · Fieser **1262 2455** · ACS **XI** · BP.**2020** · USP **42** · Ph. Eur. **9.0** (2017) **10.0** (2020) · F.C.C **11 12** · BOE **243**(8-10-2009) · Regulation (EU) n 231/2012 ·**HAZARDOUS:**RTECS: YR 6250000 · LD50 oral rat 8.471 mg/kg ·**SPECIFICATIONS:**

Assay (Ph. Eur.) (Deter. N) calc. a.d.s.	98,5-101,5%
Assay (USP) (HPLC)	98,0-102,0%
Identity :	
Identity according to Pharmacopoeias:	passes test
Melting range	132-134C
Maximum limit of impurities	
Appearance of solution	passes test
Alkalinity	passes test
Insoluble matter in C ₂ H ₅ OH	0,04 %

Loss on drying at 105C	1,0%
Residue on ignition (as SO4)	0,1 %
Chloride (Cl)	0,007%
Ammonium (NH4)	0,05%
Sulfate (SO4)	0,010%
Residual solvents (Ph.Eur/USP)	passes test
Biuret	0,1%
Organic impurities:	
Related compound A	0,1%
Individual unspecified impurity	0,1%
Total impurities	2,0%

Elemental impurities (ICH Q3D):

Class 1

Cd	0,5 ppm
Pb	0,5 ppm
As	1,5 ppm
Hg	1,5 ppm

Class 2A

Co	5 ppm
V	10 ppm
Ni	20 ppm

Class 2B

Tl	0,8 ppm
Au	10 ppm
Pd	10 ppm
Ir	10 ppm
Os	10 ppm
Rh	10 ppm
Ru	10 ppm
Se	15 ppm
Ag	15 ppm
Pt	10 ppm

Class 3

Li	55 ppm
Sb	120 ppm
Ba	140 ppm
Mo	25 ppm
Cu	250 ppm
Sn	600 ppm
Cr	25 ppm