Toxicological Datasheet

CREAPURE™ (CREATINE MONOHYDRATE)

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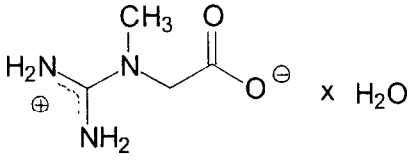
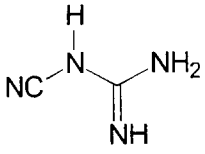
Reference

All studies were based on international accepted guidelines (EU, Organization for Economic Co-operation and Development (OECD)) under GLP (Good Laboratory Practice) conditions. The studies were performed by NOTOX B.V., Hambakenwetering 3, 5321 DD's Hertogenbosch, The Netherlands, using Creapure™ (Creatine Monohydrate, Cas-No. 6020-87-7, EINECS 200-306-6, Formula: $C_4H_9N_3O_2 \times H_2O$, molecular weight 149.1 g/mol, SKW Trostberg AG, Germany) having the following specification:

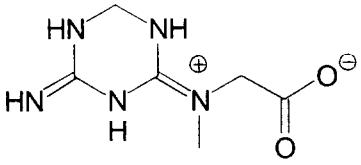


Creatine Monohydrate

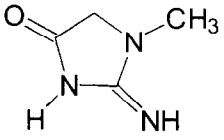
Assay:	99.99%	(HPLC)
Impurities:		
Creatinine	< 70 ppm (HPLC, limit of quantification)	
Dicyandiamide	< 20 ppm (HPLC, limit of quantification)	
Dihydrotriazine	not detectable (HPLC)	



Dicyandiamide



Dihydrotriazine



Creatinine

Heavy metals:
Hg < 0.1 ppm
Cd < 0.1 ppm
Pb < 0.1 ppm
As < 0.1 ppm

Bacterial count:

Total Aerobic Plate Count	< 100/g CFU/g
Coliforms	negative/g
E. coli	negative/g
Salmonella sp.	negative/25g
Staphylococcus aureus	negative/g

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STUDY RESULTS

1. Acute Toxicity

1.1.	Acute oral toxicity	LD50 rat: > 2000 mg/kg Method: EC-directive 96/54/EC, Part B.1 tris "Acute-Toxicity-Oral, Acute Toxic Class Method"
1.2.	Acute intraperitoneal toxicity	LD50 mouse: > 2000 mg/kg Method: EC-directive 96/54/EC, Part B.1 tris "Acute-Toxicity-Oral, Acute Toxic Class Method"

2. Local Tolerance

2.1.	Skin irritation	rabbit: No skin irritation Classification: none Method: Directive 92/32/EEC, Annex V, B.4.
2.2.	Eye irritation	rabbit: No eye irritation Classification: none Method: Directive 92/69/EEC B.5
2.3.	Sensitization	guinea pig: not sensitizing Classification: none Method: Magnusson & Kligman, Directive 96/54/EC, B.6

3. Mutagenicity

Not mutagenic
Method: Directive 92/69/EEC, B.14 "Mutagenicity: Salmonella typhimurium – reverse mutation assay"

4. Subactue Toxicity

rat: repeated dose (28 days) toxicity (oral)
No treatment-related findings noted, No Observed Adverse Effect Level (NOAEL) > 2000 mg/kg bw/day
Method: Directive 96/54/EEC, B.7