



1. PRODUCT AND COMPANY IDENTIFICATION

Product name: VALIDATE[®] UC1 Calibration Verification Test Kit
Product number: 701au, 701bc, 701db, 701ri, 701ro and 701vt

VALIDATE[®] products are not known to be hazardous. However, the above listed VALIDATE[®] product contains greater than 1.0% Urea. Therefore, this MSDS sheet was specifically created to provide information pertaining solely to Urea.

Intended Use: VALIDATE[®] Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

Manufacturer: Maine Standards Company, LLC
Address: 765 Roosevelt Trail
Windham, ME 04062

Emergency Phone: 800-377-9684
207-892-1300

Fax: 207-892-2266

2. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms: Carbamide, Carbonyldiamide
Formula: CH₄N₂O
Molecular Weight: 60.06 g/mol
IUPAC Name: Urea
Risk Phrases: None listed
Safety Phrases: S 24/25 Avoid contact with skin and eyes.
Notes: Urea is not a known carcinogen. There is no ACGIH limit.

CAS-No.	EC-No.	Index-No.	Concentration
Urea			
57-13-6	200-315-5	-	-

3. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazards
No OSHA Hazards.

HMIS Classification
Health Hazard: 0
Flammability: 0
Physical hazards: 0

NFPA Rating
Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

Potential Health Effects

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	May cause eye irritation.
Ingestion	May be harmful if swallowed.

4. FIRST AID MEASURES

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

5. FIRE-FIGHTING MEASURES

Flammable properties

Flash point	No data available
Ignition temperature	No data available

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Avoid dust formation.

Environmental precautions

Do not let product enter drains.

Methods for cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Handling

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Storage

Keep container tightly closed in a dry and well ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

For prolonged or repeated contact use protective gloves.

Eye protection

Safety glasses

Hygiene measures

General industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	Solid
Color	White

Safety data

pH	7.5 - 9.5 at 480 g/l at 25 °C (77 °F)
Melting point	133 - 135 °C (271 - 275 °F)
Boiling point	No data available
Flash point	No data available
Ignition temperature	No data available
Lower explosion limit	No data available
Upper explosion limit	No data available
Vapor pressure	0.009 hPa (0.007 mmHg) at 20 °C (68 °F)
Density	1.335 g/cm ³
Water solubility	480 g/l at 20 °C (68 °F) - completely soluble
Partition coefficient: n-octanol/water	log Pow: -2.59 - -1.59

10. STABILITY AND REACTIVITY

Storage stability

Stable under recommended storage conditions.

Materials to avoid

Strong oxidizing agents.

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

Carbon oxides, nitrogen oxides (NO_x)

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50 Oral - rat - 8,471 mg/kg

Irritation and corrosion

Skin - rabbit - No skin irritation

Eyes - rabbit - No eye irritation

Sensitization

No data available.

Chronic exposure

Genotoxicity in vitro - mouse - lymphocyte

DNA damage

Genotoxicity in vivo - mouse - Oral

Cytogenetic analysis

Laboratory experiments have shown mutagenic effects.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Potential Health Effects**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation.

Skin

May be harmful if absorbed through skin. May cause skin irritation.

Eyes

May cause eye irritation.

Ingestion

May be harmful if swallowed.

12. ECOLOGICAL INFORMATION**Elimination information (persistence and degradability)**

No data available.

Ecotoxicity effects

Toxicity to fish LC50 - *Poecilia reticulata* (guppy) - 17,500 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates.

EC50 - *Daphnia magna* (Water flea) - 3,910 mg/l - 48 h

Further information on ecology

No data available.

13. DISPOSAL CONSIDERATIONS**Product**

Observe all federal, state and local environmental regulations.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION**DOT (US)**

Not dangerous goods.

IMDG

Not dangerous goods.

IATA

Not dangerous goods.

15. REGULATORY INFORMATION**OSHA Hazards**

No OSHA Hazards.

TSCA Status

On TSCA Inventory.

DSL Status

All components of this product are on the Canadian DSL list.

SARA 302 Components

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

No SARA Hazards.

Massachusetts Right To Know Components

No Components Listed.

Pennsylvania Right To Know Components

Urea	CAS-No.	Revision Date
	57-13-6	

New Jersey Right To Know Components

Urea	CAS-No.	Revision Date
	57-13-6	

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth, or any other reproductive defects.

16. OTHER INFORMATION**Further information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Maine Standards Company shall not be held liable for any damage resulting from handling or from contact with the above product.