

List **Material Safety Data Sheet (Documentation Requirements)**

Section 1 – Product and Company Information		
Product Name Catalog Number Product Type	BUN Kinetic CD-BUN-240 & CD-BUN-400 Clinical Chemistry Reagent	Emergency Telephone No. CHEMTREC (800) 424-9300 International CHEMTREC (703) 527-3887
Company Name Street Address City, State, Zip Code, Country	Concept Diagnostics 2527 S. Greenwood Pl., Ontario, CA 91761 USA	Company Telephone No. (909) 947-3462 Fax No. (909) 947-3162

Section 2 – Composition/Information on Ingredients			
	Chemical Names	Concentration	CAS#
BUN Reagent:	NADH	0.28 mM/L	606-68-8
	Urease	3 kU/L	9002-13-5
	Glutamate Dehydrogenase	15 kU/L	9029-12-3
	2-Oxoglutarate	4 mM	
BUN Standard:	Urea	20 mg/dl	57-13-6
Other components either non-hazardous or at concentrations below that requiring hazardous listing.			

Section 3 – Hazards Identification						
Emergency Overview:						
Note: The following information applies to the component materials at higher concentrations than present in the reagent. Although lower concentrations are present in the reagent, appropriate safety precautions should still be taken.						
NADH: There is at present no information or indication of hazardous properties. The usual precautions taken when handling chemicals should be observed. Note: slightly hazardous to water and ground.						
Urease: Label Precautionary Statements: Xn (Harmful) Harmful. Irritating to eyes, respiratory system and skin. May cause sensitization by inhalation.						
Glutamate Dehydrogenase: Caution: Avoid contact and inhalation.						
2-Oxoglutarate: N/A						
Urea: N/A						
	HMIS Rating			NFPA Rating		
Chemical Names	Health	Flammability	Reactivity	Health	Flammability	Reactivity
NADH	N/A	N/A	N/A	N/A	N/A	N/A
Urease	3*	0	0	3	0	0
Glutamate dehydrogenase	2	0	0	2	0	0
2-Oxoglutarate	1	0	0	1	0	0
Urea	0	0	0	0	0	0
	*additional chronic hazards present					
For additional information on toxicity, please refer to section 11.						

Section 4 – First Aid Measures	
Skin:	In case of skin contact, immediately flush area with plenty of water for at least 15 minutes.
Eyes:	In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician if necessary.
Ingestion:	If swallowed, wash out mouth with water provided person is conscious. Call a physician.
Inhalation:	If inhaled, remove to fresh air. If not breathing give artificial respiration, but NOT by mouth-to-mouth resuscitation. If breathing is difficult, give oxygen. Call a physician.

Section 5- Fire and Explosive Hazard Data		
Flash Point N/A	Autoignition Temp N/A	Flammability N/A
Extinguishing Media Water spray. Carbon dioxide, dry chemical powder, or appropriate foam. Suitable: Use extinguishing media appropriate to surrounding fire conditions.		
Firefighting Measures Protective Equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Specific Hazard(s): Urea & NADH: Emits toxic fumes under fire conditions.		

Section 6 – Accidental Release Measures	
Procedure to be Followed in Case of Leak or Spill Ventilate the area. Absorb on inert material. Place material and contaminated disposables into a suitable container, seal, label and hold for disposal. Wash spill site after material pickup is complete.	Methods for Disposal Refer to section 13.
Procedures of Personal Precaution(s) Exercise appropriate precautions to avoid direct contact with skin or eyes. Refer to section 8.	

List	Material Safety Data Sheet (Documentation Requirements)
-------------	--

BUN Kinetic		
Section 7 – Handling and Storage		
Handling Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure. Avoid inhalation or ingestion. Do not pipette by mouth. Wash thoroughly after handling. Wash contaminated clothing before reuse. Refer to Section 8		
Storage Suitable: Keep tightly closed. Store at 2-8°C. Protect from light.		
Section 8 – Exposure Controls / PPE		
Engineering Controls Safety shower and eyewash. Ventilation: General room ventilation is satisfactory.	Personal Protective Equipment Respiratory Protection: None required where adequately ventilated. Protective Clothing: lab coat Protective Gloves: latex or rubber gloves Eye Protection: safety glasses or goggles Other Protective Equipment: Use a safety pipette device.	
Section 9 - Physical Data		
Boiling Point N/A	Melting Point N/A	Specific Gravity (g/cm³) (water = 1.0) Working reagent > 1.000
Odor No Significant Odor	Solubility in Water Soluble	Appearance Physical State: Solid
Section 10 – Stability and Reactivity		
Stability Stable	Conditions to Avoid Excess heat, flame, or pressure	Materials to Avoid Strong oxidizing agents.
Hazardous Decomposition Products carbon monoxide, carbon dioxide, nitrogen oxides, phosphorus oxides		Hazardous Polymerization Will not occur.
Section 11 – Toxicological information		
NADH:		
Route of exposure There is at present no information or indication of hazardous properties.		
Signs and Symptoms of Exposure To the best of our knowledge, the chemical, physical and toxicological properties of have not been thoroughly investigated.		
Urease:		
Route of exposure Skin Contact: Causes skin irritation. Skin Absorption: May be harmful if absorbed through the skin. Eye Contact: Causes eye irritation. Inhalation: Material is irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled. Ingestion: May be harmful if swallowed.		
Sensitization Respiratory: May cause allergic respiratory reaction.		
Signs and Symptoms of Exposure To the best of our knowledge, the chemical, physical and toxicological properties of have not been thoroughly investigated.		
Glutamate Dehydrogenase:		
Route of exposure Skin Contact: May cause skin irritation. Skin Absorption: May be harmful if absorbed through the skin. Eye Contact: May cause eye irritation. Inhalation: May be harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract. Ingestion: May be harmful if swallowed.		
Sensitization Sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.		
Signs and Symptoms of Exposure To the best of our knowledge, the chemical, physical and toxicological properties of have not been thoroughly investigated.		
2-Oxoglutarate:		
Route of exposure Skin Contact: May cause skin irritation. Eye Contact: May cause eye irritation.		
Signs and Symptoms of Exposure To the best of our knowledge, the chemical, physical and toxicological properties of have not been thoroughly investigated.		

List **Material Safety Data Sheet (Documentation Requirements)**

BUN Kinetic

Section 11 – Toxicological Information (continued)

Urea:
Route of exposure
 Skin Contact: May cause skin irritation.
 Skin Absorption: May be harmful if absorbed through the skin.
 Eye Contact: May cause eye irritation.
 Inhalation: May be harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract.
 Ingestion: May be harmful if swallowed.

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

Toxicity Data: Urease

Species:	Dose:	Route of Application:	Result:	Remarks
Rat	48 mg/kg	Intraperitoneal	LD50	Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Lacrimation. Behavioral: Sleep. Kidney, Ureter, Bladder: Urine volume increased.
Rat	20 mg/kg	Intravenous	LD50	Behavioral: Somnolence (general depressed activity). Behavioral: Convulsions or effect on seizure threshold.
Mouse	50 mg/kg	Intraperitoneal	LD50	Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Lacrimation. Behavioral: Sleep. Kidney, Ureter, Bladder: Urine volume increased.
Mouse	58 mg/kg	Subcutaneous	LD50	--
Rabbit	25 mg/kg	Intraperitoneal	LD50	Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Lacrimation. Behavioral: Sleep. Kidney, Ureter, Bladder: Urine volume increased.
Rabbit	6 mg/kg	Intravenous	LD50	Behavioral: Somnolence (general depressed activity). Behavioral: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Dyspnea.
Guinea pig	35 mg/kg	Intraperitoneal	LD50	Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Lacrimation. Behavioral: Sleep. Kidney, Ureter, Bladder: Urine volume increased.

Note: Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. (RTECS# YU1700000)

Toxicity Data: Urea

Species:	Dose:	Route of Application:	Result:	Remarks:
Rat	8471 mg/kg	Oral	LD50	--
Rat	>5 g/kg	Intraperitoneal	LD50	--
Rat	8200 mg/kg	Subcutaneous	LD50	Behavioral: Altered sleep time (including change in righting reflex). Behavioral: Change in motor activity (specific assay). Behavioral: Antipsychotic.
Rat	5300 mg/kg	Intravenous	LD50	Behavioral: Altered sleep time (including change in righting reflex). Behavioral: Change in motor activity (specific assay). Behavioral: Antipsychotic.
Rat	567 mg/kg	Intratracheal	LD50	Behavioral: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Dyspnea. Blood: Methemoglobinemia-Carboxyhemoglobin.
Mouse	11000 mg/kg	Oral	LD50	--
Mouse	9200 mg/kg	Subcutaneous	LD50	Behavioral: Altered sleep time (including change in righting reflex). Behavioral: Change in motor activity (specific assay). Behavioral: Antipsychotic.
Mouse	4600 mg/kg	Intravenous	LD50	Behavioral: Altered sleep time (including change in righting reflex). Behavioral: Change in motor activity (specific assay). Behavioral: Antipsychotic.

Irritation Data: Urea

Species:	Dose/Exposure Time/Frequency:	Route of Application:	Remarks:
Rabbit	--	Eyes	No irritation effect
Rabbit	--	Skin	No irritation effect
Human	22 mg / 3D / I	Skin	Mild irritation effect

Chronic Exposure – Carcinogen: Urea

Species:	Dose/Exposure Time/Frequency:	Route of Application:	Result:
Rat	821 g/kg / 1Y / C	Oral	Tumorigenic: Neoplastic by RTECS criteria. Blood: Tumors. Blood: Lymphomas including Hodgkin's disease.
Mouse	394 g/kg / 1Y / C	Oral	Tumorigenic: Neoplastic by RTECS criteria. Blood: Tumors. Blood: Lymphomas including Hodgkin's disease.

List **Material Safety Data Sheet (Documentation Requirements)**

BUN Kinetic					
Section 11 – Toxicological Information (continued)					
Chronic Exposure – Mutagen: Urea					
Result: Laboratory experiments have shown mutagenic effects.					
<u>Species:</u>	<u>Dose:</u>	<u>Route</u>	<u>Exposure Time</u>	<u>Cell Type:</u>	<u>Mutation Test:</u>
Human	600 mmol/L	--	--	Lymphocyte	DNA inhibition
Human	50 mmol/L	--	--	Leukocyte	Cytogenetic analysis
Mouse	628 mmol/L	--	--	Lymphocyte	DNA damage
Mouse	100 g/kg	Oral	5D	--	Cytogenetic analysis
Mouse	265 mmol/L	--	--	Lymphocyte	Mutation in mammalian somatic cells.
Hamster	8 mmol/L	--	--	Fibroblast	DNA damage
Hamster	16 g/L	--	24H	Fibroblast	Cytogenetic analysis
Hamster	13 g/L	--	--	Lung	Cytogenetic analysis
Chronic Exposure – Reproductive Hazard: Urea					
<u>Species:</u>	<u>Dose:</u>	<u>Route of Application:</u>	<u>Exposure Time</u>	<u>Result:</u>	
Woman	1400 mg/kg	Intraplacental	(16W PREG)	Effects on Fertility: Abortion.	
Woman	1600 mg/kg	Intraplacental	(16W PREG)	Effects on Fertility: Abortion.	
Monkey	6 g/kg	Intrauterine	(18W PREG)	Effects on Fertility: Abortion.	
Note: Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. (RTECS# YR6250000)					
Section 12 – Ecological Information					
No data available.					
Section 13 – Disposal Considerations					
Appropriate Method of Disposal of Substance or Preparation					
Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.					
Section 14 – Transport Information					
DOT					
Proper Shipping Name: None					
Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.					
Is not subject to current regulations for transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO)					
IATA					
Non-Hazardous for Air Transport: Non-hazardous for air transport.					
Section 15 – Regulatory Information					
NADH:			NADH:		
EC Directives Classification:			US Classification and Label Text		
Labeling is not required in accordance with EEC directive 67/548 and 99/45.			US Statements: N/A		
German Regulatory Information			US Regulatory Information		
Not subject to German regulations for flammable liquids (Betriebssicherheits VO)			SARA Listed: No		
			TSCA Inventory Item: No		
Urease:			Urease:		
EU Directives Classification			US Classification and Label Text		
Symbol of Danger: Xn			US Statements		
Indication of Danger: Harmful.			Indication of Danger: Harmful.		
R: 36/37/38 42			Risk Statements: Irritating to eyes, respiratory system and skin.		
Risk Statements: Irritating to eyes, respiratory system and skin.			May cause sensitization by inhalation.		
May cause sensitization by inhalation.			Safety Statements: Do not breathe dust. Avoid contact with skin.		
S: 22 24 26 36/37			In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing and gloves.		
Safety Statements: Do not breathe dust. Avoid contact with skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing and gloves.			US Regulatory Information		
Canadian Regulatory Information			SARA Listed: No		
WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.			TSCA Inventory Item: Yes		
DSL: No, NDSL: No					

List	Material Safety Data Sheet (Documentation Requirements)
-------------	--

BUN Kinetic	
Section 15 – Regulatory Information (continued):	
<p>Glutamate Dehydrogenase: Canadian Regulatory Information WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR. DSL: No, NDSL: No</p>	<p>Glutamate Dehydrogenase: US Classification and Label Text US Statements: Caution: Avoid contact and inhalation. US Regulatory Information SARA Listed: No</p>
<p>2-Oxoglutarate: Canadian Regulatory Information WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR. DSL: No, NDSL: No</p>	<p>2-Oxoglutarate: US Classification and Label Text US Statements: N/A US Regulatory Information SARA Listed: No TSCA Inventory Item: No</p>
<p>Urea: Canadian Regulatory Information WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR. DSL: Yes, NDSL: No</p>	<p>Urea: US Classification and Label Text US Statements: N/A US Regulatory Information SARA Listed: No TSCA Inventory Item: Yes</p>
Section 16 – Other Information	
<p>This Product is labeled in accordance with CFR21 (Food and Drugs), Section 809.10.</p>	
<p>The information contained herein has been compiled from data presented in various technical sources believed to be accurate. We make no warranties, express or implied, and assume no liability in connection with the use of this information. It is the user's responsibility to determine the suitability of this information and to assure the adoption of necessary safety precautions.</p>	
<p>N/A - Not Applicable or No Information Available</p>	