



SAFETY DATA SHEET

1. Product and Company Identification

Material name	Bilirubin Total R1 Reagent and Bilirubin Direct (Sulfanilic/nitrite) R1 and R3 Reagent
Version #	4
Issue date	2012-06-01
Revision date -	2023-06-28
Supersedes date -	
CAS #	Mixture
Kit number	C305 series, V305 series, C314 series, V314 series
Product use	For the IN VITRO quantitative measurement of either direct bilirubin or total bilirubin in serum and plasma.
Manufacturer information	
Corporate Headquarters	Catachem 353 Christian Street Oxford, CT 06478 www.catacheminc.com Phone: +1203-262-0330
Emergency Telephone Numbers	+1203-232-1979

2. Hazards Identification

Physical state	Liquid.
Appearance	Clear liquid
Emergency overview	Health injuries are not known or expected under normal use.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	In high concentrations, vapors may be irritating to the respiratory system.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes.
Chronic effects	No data available.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

4. First Aid Measures

First aid procedures

Eye contact

In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact

For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion

If material is ingested, immediately contact a poison control center.

Notes to physician

Provide general supportive measures and treat symptomatically.

General advice

If you feel unwell, seek medical advice.

5. Fire Fighting Measures

Flammable properties

This product is not flammable.

Extinguishing media

Suitable extinguishing

media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing

media

None known.

Protection of firefighters

Specific hazards arising

from the chemical

None known.

Protective equipment and

precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion

Products

None known.

6. Accidental Release Measures

Personal precautions

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions

Do not allow to enter drains, sewers or watercourses.

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up

Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information

Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
Storage	Store at 15-30°C (59-89°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.
Personal protective equipment	
Eye / face protection	Wear approved safety glasses or goggles.
Skin protection	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Under normal conditions, respirator is not normally required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Colorless
Physical state	Liquid.
Form	Liquid.
Color	Colorless
Odor	Odorless
Odor threshold	Not available.
pH	<2.0 @ (25°C)
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not applicable.
Solubility (water)	Soluble.
Specific gravity	1-1.1
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
Evaporation rate	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	No data available.
Incompatible materials	No data available.

Hazardous decomposition

Products None known.

Possibility of hazardous

Reactions Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization Not classified.

Acute effects May cause discomfort if swallowed.

Local effects Ingestion may cause irritation and nausea.

Chronic effects No data available.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

Epidemiology No epidemiological data is available for this product.

Mutagenicity Not classified.

Reproductive effects Not classified.

Symptoms and target organs Direct contact with skin and eyes may cause irritation.

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation /**Accumulation**

Not available.

Mobility in environmental

media The product is completely soluble in water.

13. Disposal Considerations

Disposal instructions Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

Waste from residues / unused

products Dispose in accordance with all applicable regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT Not regulated as a hazardous material by DOT.

IATA Not regulated as dangerous goods.

IMDG Not regulated as dangerous goods.

TDG Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpart. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lb.) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely No

hazardous substance (40

CFR 355, Appendix A)

Section 311/312

(40 CFR370) No

Drug Enforcement

Administration (DEA) (21 CFR

1308.11-15) Not controlled

Canadian regulations 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.

WHMIS status Non-controlled

Inventory status

Country(s) or region Inventory name On inventory (yes/no)*

Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	
United States		
& Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 0

Flammability: 0

Physical hazard: 0

NFPA ratings Health: 0

Flammability: 0

Instability: 0

Disclaimer The above information is believed to be correct, but does not purport to be all inclusive and should be used only as a guide. Catachem Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

1. Product and Company Identification

Material name Direct and Total Bilirubin R2 Reagent component

Version # 3

Issue date 2012-06-01

Revision date - 2021-12-08

Supersedes date -

CAS # Mixture

Kit number C304 series, V304 series, C314 series, V314 series

Product use For the IN VITRO quantitative measurement of direct and total bilirubin in serum and plasma.

Manufacturer information

Corporate Headquarters

Catachem

353 Christian Street Oxford, CT 06478

www.catacheminc.com

Phone: +1203-262-0330

Emergency Telephone

Numbers +1203-232-1979

2. Hazards Identification

Physical state	Liquid
Appearance	Clear, colorless
Emergency overview	Health injuries are not known or expected under normal use.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	May be irritating to the respiratory system.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes.
Chronic effects	No data available.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

4. First Aid Measures

First aid procedures	
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Ingestion	If material is ingested, immediately contact a poison control center.
Notes to physician	Provide general supportive measures and treat symptomatically.
General advice	If you feel unwell, seek medical advice.

5. Fire Fighting Measures

Flammable properties	This product may be flammable at temperatures in excess of 100 C.
Extinguishing media	
Suitable extinguishing	

media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.
Protection of firefighters	
Specific hazards arising from the chemical	None known.
Protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
Hazardous combustion Products	None known.

6. Accidental Release Measures

Personal precautions	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Do not allow to enter drains, sewers or watercourses.
Methods for containment	Dilute with water.
Methods for cleaning up	After dilution with water absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
Other information	Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
Storage	Store at 15-30°C (59-86°C). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.
Personal protective equipment	
Eye / face protection	Wear approved safety glasses or goggles.
Skin protection	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Under normal conditions, respirator is not normally required.

**General hygiene
considerations**

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Clear colorless Liquid
Physical state	Clear colorless
Form	Liquid
Color	Clear colorless
Odor	Odorless
Odor threshold	Not available.
pH	<2.0 @ (25°C)
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not applicable.
Solubility (water)	Soluble.
Specific gravity	N/A
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
Evaporation rate	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	No data available.
Incompatible materials	No data available.
Hazardous decomposition	
Products	None known.
Possibility of hazardous Reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization	Not classified.
Acute effects	May cause discomfort if swallowed.
Local effects	Ingestion may cause irritation and nausea.
Chronic effects	No data available.
Carcinogenicity	Not classifiable as to carcinogenicity to humans.
Epidemiology	No epidemiological data is available for this product.
Mutagenicity	Not classified.
Reproductive effects	Not classified.

Symptoms and target organs	Direct contact with skin and eyes may cause irritation.
Further information	No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulation / Accumulation	Not available.
Mobility in environmental media	The product is completely soluble in water.

13. Disposal Considerations

Disposal instructions	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
Waste from residues / unused products	Dispose in accordance with all applicable regulations.
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CERCLA (Superfund) reportable quantity (lb.) (40 CFR 302.4)	None
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - No Delayed Hazard - No

Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
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US. Pennsylvania RTK - Hazardous Substances

Not regulated.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions	Use in accordance with supplier's recommendations.
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 Instability: 0

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