

Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product Name: **Calibration Control Kit**
 Product Number: PCD4000
 Brand: Hygiena

1.2 Recommended use and restrictions on use

Identified use: Calibration verification of Hygiena SystemSURE Plus and EnSURE luminometers
 Restriction on use: Use per manufacturer's instructions only

1.3 Details of the supplier of the safety data sheet

Company: Hygiena USA
 941 Avenida Acaso
 Camarillo, CA 93012
 USA
 Telephone: 805-388-8007
 Fax: 805-388-5531
 E-mail: info@hygiena.com

1.4 Emergency telephone number

Emergency Phone: 1-888-494-4362

2. HAZARDS IDENTIFICATION

This preparation is classified as non hazardous. The activity of C¹⁴ in the Positive Control rod is ~12 µCi. It is exempt from regulations governing Radioactive Material Safety. Per U.S. NRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 µCi is exempt and not controlled. The sealed radioactive device has been individually tested for integrity. There are no radioactive emissions on the surface of the Positive Control rod.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS No.	% by Wt.
C ¹⁴ in the Positive Control rod activity is ~12 µCi. (in solution solidified in a resin catalyst polymerized gel)	N/A	N/A
Polypropylene random copolymer tubes	N/A	N/A
Polypropylene homopolymer snap plug	N/A	N/A
Polyethylene bulb	N/A	N/A
Classification:	The activity of C ¹⁴ in the Positive Control rod is ~12 µCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C ¹⁴ with activity of up to 100 µCi is exempt and not controlled. The sealed radioactive device has been individually tested for integrity. There are no radioactive emissions on the surface of the Positive Control rod.	
Form:	Calibration Control kit contains one Positive Control and one Negative Control rod in a cardboard box. The Negative rod is an empty polypropylene random copolymer tube with a polypropylene homopolymer snap plug and polyethylene bulb. The Positive Control rod contains C ¹⁴ in solution solidified in a resin catalyst polymerized gel with activity of 12 µCi in a polypropylene tube. The snap plug and bulb are exactly the same as the Negative Control rod described above.	

4. FIRST AID MEASURES

No special measures required. The sealed radioactive device has been individually tested for integrity. There are no radioactive emissions on the surface of the Positive Control rod.

If inhaled

No special measures required. If breathed in, move person into fresh air; consult doctor in case of complaints.

In case of skin contact

No special measures required. Wash with soap and plenty of water.

4. FIRST AID MEASURES (Continued)

In case of eye contact

No special measures required. Rinse opened eye for 15 minutes under running water, then consult a doctor.

If swallowed

Rinse mouth with water and seek medical advice.

5. FIRE-FIGHTING MEASURES

Combustible. Emits potentially toxic fumes under fire conditions.

Suitable extinguishing media

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

Special protective equipment

No special measures required. Wear self contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

No special personal protective equipment required. The activity of C¹⁴ in the Positive Control rod is ~12 µCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 µCi is exempt and not controlled. The sealed radioactive device has been individually tested for integrity. There are no radioactive emissions on the surface of the Positive Control rod.

Do not use if the scintillated tip of the Positive rod is cracked or damaged. Remove or deface Label and dispose in trash.

Environmental precautions

None.

Methods for cleaning up

No special measures required.

7. HANDLING AND STORAGE

Handling

No special measures required. Handle according to GLP (Good Laboratory Practice) use as directed by manufacturer. The activity of C¹⁴ in the Positive Control rod is ~12 µCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 µCi is exempt and not controlled. The sealed radioactive device has been individually tested for integrity. There are no radioactive emissions on the surface of the Positive Control rod.

Do not use if the scintillated tip of the Positive rod is cracked or damaged. Remove or deface Label and dispose in trash.

Storage

Store in a dry place at temperature between 15°-25°C and keep in cardboard box provided to protect from light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

The activity of C¹⁴ in the Positive Control rod is ~12 µCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 µCi is exempt and not controlled. Contains no substances exceeding occupational exposure limit values. There are no radioactive emissions on the surface of the Positive Control rod.

Do not use if the scintillated tip of the Positive rod is cracked or damaged. Remove or deface Label and dispose in trash.

Personal protective equipment

No personal protective equipment required for normal use. Handle according to GLP (Good Laboratory Practices).

Respiratory protection

Not required.

Hand protection

For prolonged or repeat contact use protective gloves.

Eye protection

Not required.

Hygiene measures

General Industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Form	Calibration Control kit contains one Positive Control rod and one Negative Control rod in a cardboard box. The Negative rod is an empty polypropylene random copolymer tube with a polypropylene homopolymer snap plug and polyethylene bulb. The Positive Control rod contains C ¹⁴ in solution solidified in a resin catalyst polymerized gel with activity of 12 μCi in a polypropylene tube. The snap plug and bulb are exactly the same as the negative Control rod described above. There are no radioactive emissions on the surface of the Positive Control rod.
	Color	N/A
Safety Data	pH	N/A
	Odor	N/A
	Melting point	N/A
	Boiling point	N/A
	Flash point	N/A
	Vapor Pressure	N/A
	Lower exposure limit	N/A
	Upper exposure limit	N/A
Water solubility	N/A	

10. STABILITY AND REACTIVITY

Storage stability

Stable. Store in a dry place at temperature between 15°-25°C. Keep in cardboard box provided to protect from light. Avoid extreme temperatures both high and low.

Materials to avoid

None.

Hazardous decomposition products

Plastic components may emit toxic fumes if combusted.

11. TOXICOLOGICAL INFORMATION

This preparation is classified as non hazardous. The activity of C¹⁴ in the Positive Control rod is ~12 μCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 μCi is exempt and not controlled. There are no radioactive emissions on the surface of the Positive Control rod. When used and handled according to specifications, the product does not have any harmful effects according to information provided to us.

Do not use if the scintillated tip of the Positive rod is cracked or damaged. Remove or deface Label and dispose in trash.

12. ECOLOGICAL INFORMATION

No environmental hazard is anticipated provided that the material is handled and disposed of with due care and attention.

13. DISPOSAL CONSIDERATIONS

Product

The product is not considered Radioactive material waste. Deface or remove Label and dispose in trash. Observe local, State and Federal environmental regulations. The activity of C¹⁴ in the Positive Control rod is ~12 μCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 μCi is exempt and not controlled. There are no radioactive emissions on the surface of the Positive Control rod.

Do not use if the scintillated tip of the Positive rod is cracked or damaged. Remove or deface Label and dispose in trash.

Contaminated packaging

Dispose of as unused product. There are no radioactive emissions on the surface of the Positive Control rod.

14. TRANSPORT INFORMATION

Not subject to transport regulations.

15. REGULATORY INFORMATION

Labeling according to Globally Harmonized System (GHS) of classification and labeling of chemicals. The activity of C¹⁴ in the Positive Control rod is ~12 μCi. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C¹⁴ with activity of up to 100 μCi is exempt and not controlled.

No special labeling required.

16. OTHER INFORMATION

This preparation is classified as non hazardous.

The activity of C^{14} in the Positive Control rod is $\sim 12 \mu\text{Ci}$. It is exempt from regulations governing Radioactive Material Safety. Per USNRC, Nuclear Regulatory Commission Schedule B 30.71 and Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20); C^{14} with activity of up to $100 \mu\text{Ci}$ is exempt and not controlled. There are no radioactive emissions on the surface of the Positive Control rod.

Do not use if the scintillated tip of the Positive rod is cracked or damaged. Remove or deface Label and dispose in trash.

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

Preparation Information

Hygiena USA
Product Safety
1-888-494-4362

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End of Safety Data Sheet