GEX CORPORATION

Product Specification (PS)
(P8100) Yellow/Purple Radiation Indicators
Reaction Starts at 3kGy

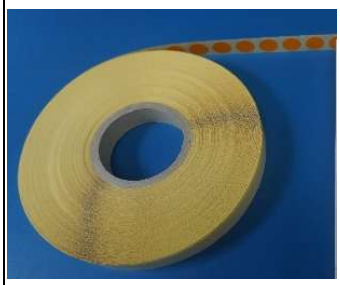
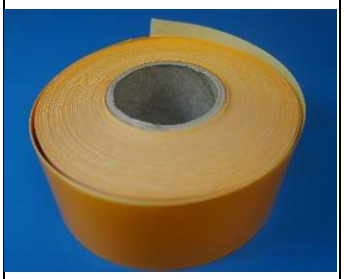
1. Product Description

GEX PRODUCT ID	PRODUCT NAME
P8100	Yellow/Purple Radiation Indicators

2. Product Description

P8100 Series Radiation Indicators are Type 1 process chemical indicators, and exhibit an obvious, visual color change from yellow to purple when exposed to radiation. Radiation Indicators quickly allow the user to visually determine whether the indicator has been irradiated. The product can also be useful in a variety of research applications.

Radiation Indicators are not dosimeters, and do not provide a quantitative measurement of absorbed dose. They are not recommended to be used as the sole verification method to assess product conformity to specification.

Product Number:	P8101	P8102	P8103
Description	Radiation Indicator Dots 13mm diameter 1,000 dots per roll	Radiation Indicator Dots 13mm diameter 5,000 dots per roll	Radiation Indicator Paper 50m x 48mm roll (special order)
Product Photo			

3. Intended Use

The Radiation Indicator is designed for the qualitative assessment of radiation exposure for use in Gamma, Electron beam, and X-ray radiation process applications. P8100 Series Radiation Indicators are thin, flexible and have adhesive properties allowing them to be attached to most surfaces.

Radiation Indicators are a convenient way to:

- Visually distinguish between irradiated and non-irradiated products within a radiation processing facility
- Monitor multi-pass and multiple-sided processes
- Maintain inventory and quality control

4. Product Specifications

Physical Properties

Substrate:	~70 µm paper
Adhesive:	Ucecryl PC 91 (Acrylic-based emulsion)
Release Liner:	~70 µm Silicone Release Liner
Indicator Ink:	PVB based coating

Performance Characteristics

Process:	Radiation (Gamma and Electron Beam)
Chemical indicator:	Initial color: Yellow Signal color: Red or reddish-violet (purple) color.
Reaction start point:	Begins at 3kGy
Color transition saturation	~25 kGy
Result availability:	Immediately following exposure to radiation
Description of result:	Un-irradiated Indicators are a bright, yellow color as shown in the image below at 0 kGy. When irradiated, the indicators undergo a chemical alteration and reliably activate and change color at 3 kGy. The indicators continue to change color and progressively develop to darker shades of purple at radiation doses of 10 kGy and above.

Unexposed	~3 kGy	~5 kGy	~10 kGy	~15 kGy	~25 kGy
					

Colors shown are representations of initial and signal colors but may vary from actual use.

CAUTION

The signal color achieved from exposure to radiation may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, radiation dose etc.) For a Type 1 Process Indicator, a color change to shade of Red/Violet produced during exposure to radiation which is different from the initial color is considered acceptable.

Product Package

GEX P/N	Product Description	Dimensions – product box (W × L× D)	Weight – product box
P8101	13mm Radiation Indicator Dots, (1,000 per roll)	8.3cm x 8.3cm x 1.9cm (3.25in x 3.25in x 0.75in) approx.	0.05kg (0.10 lbs.) approx.
P8102	13mm Radiation Indicator Dots 5,000 per roll	15.25cm x 15.25cm x 2.5cm (6.0in x 6.0in x 1.0in) approx.	0.21kg (0.46 lbs.) approx.
P8103*	Radiation Indicator Paper Roll	20.3cm x 20.3cm x 5.1cm (8.0in x 8.0in x 2.0in) approx.	0.73 kg (1.6 lbs.) approx.

**Special order only.*

5. Usage

For further information about usage, reference *ISO/ASTM 51539 - Guidance for Use of Radiation-Sensitive Indicators*.

1) Remove the Indicator roll from the packaging.
2) Ensure the Indicator is yellow before irradiation.
3) Apply an Indicator to a clean, plain, smooth, and dry surface.
4) Press the Indicator firmly to ensure proper adhesion.
5) Keep the remaining Indicator roll tightly closed at room temperature. (See *Storage*.)
6) Perform irradiation.
7) After irradiation, check that the indicator has changed to red or reddish violet depending on the radiation dose.

CAUTION

Testing and Inspection of indicator adhesion to the product surface is required prior to use. See Limitations/Precautions.

6. Storage

- Store the unirradiated Radiation Indicators in the original packaging.
- Store at room temperature (15-25°C). Moderate heat (up to 30°C) will not adversely affect the response of the indicators. However, extreme temperature and relative humidity environmental conditions may adversely affect the function of the indicator.
- Keep dry.
- Store in a dark container and protected from UV light. Avoid exposure to direct sunlight and intense UV light.
- Avoid exposure to acidic or basic gases.

Avoid extreme conditions of combined humidity and temperature (75% RH and 43°C) for ≥15 days of exposure.

7. Stability

The color has been shown to remain stable for approximately 15 to 18 months. However, extreme conditions of combined humidity and temperature (75% RH and 43°C) may affect stability.

The user should verify the stability under their conditions of irradiation and storage because this is not a specification.

8. Shelf Life

Expiration date is 15 months from Date of Shipment (DOS). Radiation Indicator products are supplied with a Lot Number and a "Use By" date. Users are encouraged to use the indicators on or before the "Use By" date. (Batch is assigned by GEX to identify the lot).

9. Health / Environmental

Disposal

Discard in general waste. The product is made of non-toxic materials. A Material Safety Data Sheet (MSDS) is not required, per CFR 1910.1200.

10. Limitations/Precautions

Usage limitations

- Indicators should be used for inventory and control purposes only and should never be used as a substitute for dosimetry.
- Indicators may not adhere well to certain polymers such as polypropylene, or to rough surfaces, bumpy or textured surfaces, or curved surfaces. Application on any surface should be tested by the user. Always inspect the indicator adhesion to the product surface is required prior to use.
- Infrequent false positive or false negative results may occur. Generally, any small failure of a few dots cannot be investigated for cause due to the sample size. However, all failures should be reported to GEX for tracking and trending purposes.

Environmental influences on performance

See *Storage*.

- Radiation Indicators are sensitive to any form of radiation, including sunlight. Avoid exposure to direct sunlight or intense UV lighting.
- Extreme temperature and relative humidity environmental conditions may adversely affect the functionality and/or stability of the Radiation Indicator.
- Product packaging and environmental outgassing have been shown to affect indicator performance. Customers are therefore encouraged to test the indicators under their conditions of use to ensure the indicators will meet their requirements.
- The chemical reaction which causes the color transition is a radiation specific reaction and is irreversible under most conditions. Post-exposure storage near pH basic environments such as reagents or cleaning product fumes may cause involuntary reversion of color change.

11. Shipping / Delivery

Country of origin	Manufactured in Egypt. Packaged in U.S.A.

12. Quality Assurance

GEX's Quality Management System (QMS) is ISO 9001:2015 accredited. Download certificates and more information available at ***https://www.gexcorp.com/quality.html***.

13. Related Documents

DOC. ID	TITLE
AAMI ST60	Sterilization of Health Care Products – Chemical Indicators
ISO 11140-1	Sterilization of Health Care Products – Chemical Indicators
ISO/ASTM 51539	Guidance for Use of Radiation – Sensitive Indicators

14. Revision History

DATE	CHANGE DESCRIPTION	REVISION
04/11/2025	Transferred relevant information regarding the P8100 Yellow/Purple Radiation Indicators from GEX Doc# 100-124 into the new GEX PSS Document Template. ECO 75097	A
09/19/2025	Changed the Date of Manufacture (DOM) to Date of Shipment (DOS) in Section 8 (Shelf Life). ECO 75167	B

Standard units are safety-approved and bear the test marks