

**Product range:** Assay Genie Anti-Drug Antibody Range (GXDA series) — glycerol/preserved formulation | **SDS no.:** GXDA\_MSDS\_PRESERVED | **Revision:** Version 1.0 | **Revision date:** 28 July 2026 | **Products covered:** 41

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

|                                 |                                                                                                                                                                                                                                                                                                                 |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product identifier</b>       | Assay Genie anti-drug antibody (product/SKU code in the format GXDA#####). This SDS applies to the 41 products in the GXDA range supplied in 0.01M phosphate-buffered saline, pH 7.4, with 50% (v/v) glycerol and 0.05% Proclin 300 preservative. The applicable SKUs are listed in the annex to this document. |
| <b>Product form</b>             | Mixture – purified immunoglobulin in 0.01M phosphate-buffered saline, pH 7.4, with 50% (v/v) glycerol and 0.05% Proclin 300 preservative.                                                                                                                                                                       |
| <b>Relevant identified uses</b> | Laboratory reagent for research use only (RUO). Not for use in diagnostic or therapeutic procedures, or for human or veterinary use.                                                                                                                                                                            |
| <b>Uses advised against</b>     | Any use other than the identified research use.                                                                                                                                                                                                                                                                 |
| <b>Supplier</b>                 | Assay Genie Ltd   <a href="http://www.assaygenie.com">www.assaygenie.com</a>   Technical support: <a href="mailto:techsupport@assaygenie.com">techsupport@assaygenie.com</a>   Sales: <a href="mailto:sales@assaygenie.com">sales@assaygenie.com</a>                                                            |
| <b>Registered address</b>       | Assay Genie Ltd, 25 Windsor Place, Dublin 2, D02 VY42, Ireland                                                                                                                                                                                                                                                  |
| <b>Emergency telephone</b>      | +353 1 563 9720 (Monday–Friday, 08:00–18:00 GMT). This is not a 24-hour emergency line; for medical emergencies contact your local poison centre or emergency services.                                                                                                                                         |

## SECTION 2: Hazards identification

|                                 |                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Classification (CLP/GHS)</b> | Based on available information the product as supplied is not classified as hazardous under Regulation (EC) No 1272/2008 (CLP) or UN GHS. The product contains an isothiazolinone preservative (CMIT/MIT) below the generic concentration limit for classification as a skin sensitiser.                                                          |
| <b>Label elements</b>           | No signal word, hazard pictogram or hazard statement is required for the product as supplied. Supplemental statement EUH208 ("Contains 5-chloro-2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.") is stated here as a precaution — see the note in Section 3 and confirm applicability with the exact preservative specification. |
| <b>Other hazards</b>            | The preservative may provoke an allergic skin reaction in sensitised individuals. Avoid contact with skin and eyes. No PBT/vPvB components are known. Not a physical or environmental hazard in the quantities supplied.                                                                                                                          |

### SECTION 3: Composition / information on ingredients

The product is a buffered protein solution containing glycerol as a cryoprotectant and an isothiazolinone preservative. Component concentrations are nominal and may vary slightly between batches without affecting the hazard classification.

| Component                                      | CAS No.    | Concentration     | Classification note                                                             |
|------------------------------------------------|------------|-------------------|---------------------------------------------------------------------------------|
| Antibody protein (immunoglobulin)              | —          | 0.1–1.0 mg/mL     | Not classified                                                                  |
| Glycerol                                       | 56-81-5    | 50% (v/v)         | Not classified                                                                  |
| Sodium chloride                                | 7647-14-5  | 0.4–0.9% (w/v)    | Below classification threshold                                                  |
| Disodium hydrogen phosphate                    | 7558-79-4  | 0.05–0.2% (w/v)   | Below classification threshold                                                  |
| Potassium dihydrogen phosphate                 | 7447-40-5  | 0.005–0.03% (w/v) | Below classification threshold                                                  |
| Proclin 300 (isothiazolinone biocide)          | 55965-84-9 | 0.05% (v/v)       | Contains CMIT/MIT — skin sensitiser; see note below                             |
| — 5-chloro-2-methyl-2H-isothiazol-3-one (CMIT) | 26172-55-4 | ≈ 0.0008% (w/w)   | Skin Sens. 1A. Below the 0.0015% generic concentration limit for classification |
| — 2-methyl-2H-isothiazol-3-one (MIT)           | 2682-20-4  | ≈ 0.0003% (w/w)   | Skin Sens. 1A. Below the generic concentration limit for classification         |
| Water for injection                            | 7732-18-5  | Balance           | Not classified                                                                  |

**Note on the preservative.** The isothiazolinone content is calculated from a nominal 2.3% active concentration in Proclin 300 and is therefore approximate. It sits close to the 0.0015% generic concentration limit at which CLP requires the supplemental statement EUH208 ("Contains 5-chloro-2-methyl-2H-isothiazol-3-one. May produce an allergic reaction."). Assay Genie should confirm the exact active concentration with the manufacturer and take an EHS decision on whether EUH208 is applied to the label. It is included in Section 2 of this SDS as a precaution.

### SECTION 4: First-aid measures

|                                |                                                                                                                                                                                   |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>              | Not an expected route of exposure. Move to fresh air if aerosols are inhaled and symptoms occur. Seek medical advice if symptoms persist.                                         |
| <b>Skin contact</b>            | Wash the affected area with soap and water. Remove contaminated clothing. If irritation or a skin reaction develops, seek medical advice.                                         |
| <b>Eye contact</b>             | Rinse cautiously with water for several minutes; remove contact lenses if present and easy to do. If irritation persists, seek medical attention.                                 |
| <b>Ingestion</b>               | Rinse mouth with water. Do not induce vomiting. Seek medical advice if a large amount is swallowed.                                                                               |
| <b>Most important symptoms</b> | No specific symptoms expected. Mild transient irritation possible on direct contact. An allergic skin reaction is possible in individuals already sensitised to isothiazolinones. |
| <b>Medical attention</b>       | Show this safety data sheet to the doctor in attendance.                                                                                                                          |

### SECTION 5: Firefighting measures

|                                     |                                                                                                                                |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| <b>Suitable extinguishing media</b> | Water spray, alcohol-resistant foam, dry chemical or carbon dioxide, as appropriate to the surrounding fire.                   |
| <b>Special hazards</b>              | The product is not flammable. Glycerol is combustible at high temperatures. Combustion may emit oxides of carbon and nitrogen. |
| <b>Advice for firefighters</b>      | Wear self-contained breathing apparatus and full protective clothing where required by the surrounding fire.                   |

### SECTION 6: Accidental release measures

|                                           |                                                                                                                                                                                                                                        |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal precautions</b>               | Wear gloves and eye protection. Avoid contact with skin and eyes. Ensure adequate ventilation.                                                                                                                                         |
| <b>Environmental precautions</b>          | Do not allow the product to enter drains or watercourses. The preservative is toxic to aquatic life.                                                                                                                                   |
| <b>Methods for containment / cleaning</b> | Absorb spillage with inert absorbent material, place in a suitable container and dispose of in accordance with local regulations. Wipe the area with water. Glycerol solutions are slippery — clean thoroughly to avoid a slip hazard. |
| <b>Reference to other sections</b>        | For personal protection see Section 8. For disposal see Section 13.                                                                                                                                                                    |

## SECTION 7: Handling and storage

|                                      |                                                                                                                                                                                                                                      |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Precautions for safe handling</b> | Handle in accordance with good laboratory practice. Wear appropriate PPE. Do not eat, drink or smoke when using the product. Avoid generating aerosols. Wash hands after use.                                                        |
| <b>Storage</b>                       | Store at –20°C. The 50% glycerol content prevents the solution freezing solid at –20°C, so aliquoting is not normally required. Avoid repeated freeze-thaw cycles. See the product datasheet for the SKU-specific storage statement. |
| <b>Shelf life</b>                    | Twelve months from the date of receipt under the storage conditions stated above, unless otherwise stated on the product label.                                                                                                      |

## SECTION 8: Exposure controls / personal protection

|                                      |                                                                                                                                     |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <b>Occupational exposure limits</b>  | None established for the mixture or its components at the concentrations supplied.                                                  |
| <b>Engineering controls</b>          | Normal laboratory ventilation is sufficient. Ensure eye wash facilities are available.                                              |
| <b>Personal protective equipment</b> | Nitrile or latex gloves, laboratory coat and safety glasses. Gloves should be inspected before use and hands washed after handling. |
| <b>Respiratory protection</b>        | Not normally required. Use a suitable respirator if a risk assessment indicates aerosol generation.                                 |

## SECTION 9: Physical and chemical properties

|                         |                                                                                                                                                |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Appearance</b>       | Clear to slightly opalescent, viscous aqueous solution. Colourless to pale yellow.                                                             |
| <b>Odour</b>            | Odourless or faint.                                                                                                                            |
| <b>pH</b>               | 7.0–7.4.                                                                                                                                       |
| <b>Freezing point</b>   | Does not freeze solid at –20°C (50% glycerol).                                                                                                 |
| <b>Solubility</b>       | Miscible with water.                                                                                                                           |
| <b>Viscosity</b>        | Markedly higher than water owing to the glycerol content.                                                                                      |
| <b>Flammability</b>     | Non-flammable (aqueous).                                                                                                                       |
| <b>Other properties</b> | Boiling point, flash point, vapour pressure, explosive and oxidising properties: not determined / not applicable to aqueous protein solutions. |

## SECTION 10: Stability and reactivity

|                                         |                                                                       |
|-----------------------------------------|-----------------------------------------------------------------------|
| <b>Reactivity / stability</b>           | Stable under the recommended storage and handling conditions.         |
| <b>Conditions to avoid</b>              | Elevated temperatures, direct sunlight, repeated freeze-thaw cycling. |
| <b>Incompatible materials</b>           | Strong acids and alkalis; strong oxidising and reducing agents.       |
| <b>Hazardous decomposition products</b> | None known under normal conditions of use.                            |

## SECTION 11: Toxicological information

|                                       |                                                                                                                                                                                                                                                                                                              |
|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Acute toxicity</b>                 | No toxicological data available for the mixture. Not expected to be acutely toxic at the quantities and concentrations supplied.                                                                                                                                                                             |
| <b>Skin / eye</b>                     | The preservative may cause mild irritation and, in sensitised individuals, an allergic skin reaction. Glycerol is not irritant. Transient mild irritation possible on direct eye contact.                                                                                                                    |
| <b>Sensitisation / CMR</b>            | Contains CMIT/MIT below the generic concentration limit for classification. Isothiazolinones are recognised skin sensitisers and may cause an allergic skin reaction in already-sensitised individuals. No component is a known carcinogen, mutagen or reproductive toxicant at the concentrations supplied. |
| <b>Specific target organ toxicity</b> | No data indicating specific target organ toxicity. Classification criteria are not met.                                                                                                                                                                                                                      |
| <b>Aspiration hazard</b>              | Low volatility aqueous solution. Classification criteria are not met.                                                                                                                                                                                                                                        |
| <b>Routes of exposure</b>             | Inhalation of aerosols may cause transient irritation of the upper respiratory tract. Prolonged skin contact may cause transient redness. Direct eye contact may cause transient redness and tearing. Accidental ingestion may cause transient gastrointestinal irritation.                                  |

## SECTION 12: Ecological information

|                                                 |                                                                                                                                                                                             |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ecotoxicity</b>                              | No data available for the mixture. Isothiazolinones are toxic to aquatic organisms; although the quantity supplied is very small, do not allow the product to enter drains or watercourses. |
| <b>Persistence / bioaccumulation / mobility</b> | Not determined.                                                                                                                                                                             |
| <b>PBT / vPvB</b>                               | The mixture contains no components assessed as PBT or vPvB.                                                                                                                                 |
| <b>Endocrine disrupting properties</b>          | No data indicating that the components have endocrine disrupting properties.                                                                                                                |

## SECTION 13: Disposal considerations

|                               |                                                                                                                                                                                                                                             |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Waste treatment</b>        | Dispose of contents and container in accordance with local, regional and national regulations. Where material of human or animal origin has been in contact with the product, treat consumables as potentially infectious biological waste. |
| <b>Contaminated packaging</b> | Dispose of via a licensed waste contractor in accordance with local regulations.                                                                                                                                                            |

## SECTION 14: Transport information

|                                               |                                                                                           |
|-----------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>ADR / RID / IMDG / IATA / DOT</b>          | Not classified as dangerous goods for transport. No UN number assigned.                   |
| <b>UN number / proper shipping name</b>       | Not applicable.                                                                           |
| <b>Transport hazard class / packing group</b> | Not applicable.                                                                           |
| <b>Special precautions</b>                    | None. Ship with cold packs or on dry ice as required to maintain the storage temperature. |

## SECTION 15: Regulatory information

|                                   |                                                                                                                                                                                                                         |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EU regulations</b>             | This SDS has been prepared in accordance with Regulation (EC) No 1907/2006 (REACH) Annex II, as amended, and Regulation (EC) No 1272/2008 (CLP). Supplemental labelling under EUH208 may apply — see Sections 2 and 3.  |
| <b>US regulations</b>             | This SDS is also intended to meet the format requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012). TSCA, SARA 311/312, SARA 313, CERCLA and California Proposition 65: not applicable. |
| <b>Chemical safety assessment</b> | No chemical safety assessment has been carried out for this mixture.                                                                                                                                                    |
| <b>Product status</b>             | For Research Use Only (RUO).                                                                                                                                                                                            |

## SECTION 16: Other information

|                    |                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Revision</b>    | Version 1.0, 28 July 2026. First issue.                                                                                                                                                                                                                                                                                                                                    |
| <b>Scope</b>       | This SDS covers the 41 GXDA products supplied in 0.01M phosphate-buffered saline, pH 7.4, with 50% (v/v) glycerol and 0.05% Proclin 300 preservative. The Assay Genie GXDA range comprises two formulations and is covered by two separate safety data sheets; check the buffer stated on the product datasheet to identify which applies.                                 |
| <b>Prepared by</b> | Assay Genie (draft prepared for QA/EHS review).                                                                                                                                                                                                                                                                                                                            |
| <b>Disclaimer</b>  | The information above relates only to the specific product range and does not constitute a warranty of any kind. It is provided in good faith and is believed to be correct as of the revision date. Composition data are taken from supplier product specifications. It is the user's responsibility to ensure safe conditions of use and to comply with applicable laws. |

## Annex: products covered by this safety data sheet (41)

This SDS applies to the following Assay Genie SKUs. Products in the GXDA range not listed here are covered by the other GXDA safety data sheet.

|           |           |           |           |           |           |
|-----------|-----------|-----------|-----------|-----------|-----------|
| GXDA00173 | GXDA00174 | GXDA00175 | GXDA00176 | GXDA00177 | GXDA00178 |
| GXDA00179 | GXDA00180 | GXDA00181 | GXDA00183 | GXDA00184 | GXDA00185 |
| GXDA00187 | GXDA00188 | GXDA00189 | GXDA00190 | GXDA00191 | GXDA00192 |
| GXDA00193 | GXDA00194 | GXDA00195 | GXDA00196 | GXDA00197 | GXDA00198 |

|           |           |           |           |           |           |
|-----------|-----------|-----------|-----------|-----------|-----------|
| GXDA00199 | GXDA00200 | GXDA00201 | GXDA00202 | GXDA00203 | GXDA00204 |
| GXDA00205 | GXDA00214 | GXDA00215 | GXDA00216 | GXDA00217 | GXDA00287 |
| GXDA00291 | GXDA00292 | GXDA00303 | GXDA00304 | GXDA00305 |           |

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— End of Safety Data Sheet —