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SAFETY DATA SHEET

1. Identification of the substance/mixture and of the company/undertaking

Identification of the substance/preparation

Product code NIPT-100
Product name iSAFE™ Non-Invasive Prenatal Test Assay
For Trisomy 21, Trisomy 18, Trisomy 13 Detection,
Fetal Fraction, and Gender Determination

Company/Undertaking Identification

Atila Biosystems Inc.
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**For Research Use Only. Not for use in diagnostic procedures.
Not intended for human or animal diagnostic or therapeutic uses.**

2. Hazards identification

GHS - Classification

Signal Word
Not Hazardous

Health Hazard
Not hazardous

Physical Hazards
Not hazardous

Hazard statements
Not hazardous

Precautionary statements
Not hazardous

Revision Date 01-March-2023
Product code NIPT-100

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Product name iSAFE™ NIPT Assay

**Principle Routes of Exposure/
Potential Health effects**

Eyes	none
Skin	none
Inhalation	none
Ingestion	none

Specific effects

Carcinogenic effects	none
Mutagenic effects	none
Reproductive toxicity	none
Sensitization	none

Target Organ Effects None under normal use conditions

HMIS

Health	0
Flammability	0
Reactivity	0

3. Composition/information on ingredients

Chemical Name	CAS-No	EINECS-No	Weight %
GLYCEROL	56-81-5	-	50
TRIS Base	77-86-1	201-064-4	0.12
Sodium Azide	26628-22-8	247-852-1	<0.01

Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. We recommend handling all chemicals with caution.

4. First aid measures

Skin contact	Wash off immediately with plenty of water for at least 15 minutes. Remove and wash contaminated clothing before re-use. Immediate medical attention is required.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required.
Ingestion	Call a physician or Poison Control Centre immediately. Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice.
Inhalation	Move to fresh air. If not breathing, give artificial respiration. Call a physician or Poison Control Centre immediately.
Notes to physician	Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media	Water spray. Carbon dioxide (CO ₂). Foam. Dry chemical.
Special protective equipment for firefighters	Wear self-contained breathing apparatus and protective suit.

6. Accidental release measures

Personal precautions Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment.

Methods for cleaning up Soak up with inert absorbent material.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

See Section 12 for additional information.

7. Handling and storage

Handling Always wear recommended Personal Protective Equipment. No special handling advice required.

Storage Assay storage temperature as per Instructions for Use: -20°C ± 5°C. Keep in properly labeled containers

8. Exposure controls/personal protection

Exposure limits

Chemical Name	OSHA PEL	OSHA PEL (Ceiling)	ACGIH OEL (TWA)	ACGIH OEL (STEL)
GLYCEROL	15 mg/m ³ 5 mg/m ³	none	10 mg/m ³	none
TRIS Base	none	none	none	none
Sodium Azide	none	none	none	none

Engineering measures Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Personal Protective Equipment requirements are dependent on the user institution's risk assessment and are specific to the risk assessment for each laboratory where this material may be used.

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment.

Hand protection Impervious gloves.

Eye protection Safety glasses with side-shields.

Skin and body protection. Lightweight protective clothing.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls Prevent product from entering drains. Do not allow material to contaminate ground water system.

9. Physical and chemical properties

General Information

Form liquid

Appearance No information available

Odor No information available

Boiling Point/Range °C no data available °F no data available

Melting point/range °C no data available °F no data available

Flash point °C no data available °F no data available

Autoignition temperature °C no data available °F no data available

Oxidizing properties No information available.

Water solubility soluble

10. Stability and reactivity

Stability	Stable under normal conditions.
Materials to avoid	Sodium azide may react with lead and copper plumbing to form highly explosive metal azides.
Hazardous decomposition products	No information available.
polymerization	None under normal processing.

11. Toxicological information

Acute toxicity

Chemical Name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50 (inhalation, rat/mouse)
GLYCEROL	= 12600 mg/kg (Rat)	no data available	no data available
TRIS Base	= 5900 mg/kg (Rat)	no data available	no data available
Sodium Azide	= 27 mg/kg (Rat)	no data available	no data available

Principle Routes of Exposure/

Potential Health effects

Eyes	none
Skin	none
Inhalation	none
Ingestion	none

Carcinogenic effects	none
Mutagenic effects	none
Reproductive toxicity	none
Sensitization	none

Target Organ Effects	None under normal use conditions
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12. Ecological information

Ecotoxicity effects	Daphnia magna (Water flea)
Mobility	see log Pow
Biodegradation	No information available.
Bioaccumulation	No information available.

Chemical Name	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	log Pow
GLYCEROL 56-81-5		Daphnia magna EC50>500 mg/L (24 h)			logPow-1.76

13. Disposal considerations

Dispose of in accordance with local regulations.

14. Transport information

IATA

Proper shipping name	Not classified as dangerous in the meaning of transport regulations
Hazard class	none
Subsidiary Class	none
Packing group	none
UN-No	none

15. Regulatory information

Component	TSCA
GLYCEROL 56-81-5 (10-30)	Listed
TRIS Base 77-86-1 (1-10)	Listed
Sodium Azide 26628-22-8 (<0.01)	Listed

U.S. Federal Regulations

SARA 313

This product contains the following toxic chemical(s) subject to the notification requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986. This law requires certain manufacturers to report on annual emissions of specified chemicals and chemical categories. Please note that if you repackage, or otherwise redistribute, this product to industrial customers, a notice similar to this one should be sent to those customers:

Chemical Name
Sodium Azide

CAS-No
26628-22-8

Weight %
<0.01

SARA 313 - Threshold Values
1.0

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product does not contain HAPs.

U.S. State Regulations

Chemical Name	Massachusetts - RTK	New Jersey - RTK	Pennsylvania - RTK	Illinois - RTK	Rhode Island - RTK
GLYCEROL	Listed	-	Listed	-	Listed
TRIS Base	-	-	-	-	-
Sodium Azide	Listed	-	Listed	-	Listed

California Proposition 65

This product does not contain chemicals listed under Proposition 65

WHMIS Hazard Class

D2B Toxic materials



This product has been classified according to the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR

16. Other information

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Reason for Revision

(M)SDS sections updated.

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The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS MSDS DOES NOT CONSTITUTE A WARRENTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PUPOSE.

End of Safety Data Sheet