

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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ViraTrans Transport Medium B1029-35C, B1029-35D

Revision 2

Revision date 2015-06-01

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

1.1. Product identifier

Product name	ViraTrans Transport Medium B1029-35C, B1029-35D
Product code	652790

1.3. Details of the supplier of the safety data sheet

Company	Trinity Biotech
Address	IDA Business Park Bray Co. Wicklow Ireland
Web	www.trinitybiotech.com
Telephone	+353 1 276 9800
Fax	+353 1 276 9883
Email	info@trinitybiotech.com

Local Supplier

Company	Trinity Biotech USA
Address	2823 Girts Rd Jamestown NY 14701 USA
Telephone	+1 800-325-3424
Fax	+1 716-487-1419

1.4. Emergency telephone number

	Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Main hazards	No Significant Hazard
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2.2. Label elements

Risk phrases	No Significant Hazard
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

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3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Fetal Bovine Serum TM030							
MEM WITH HANKS SALTS 011-047							
HEPES Free Acid TM005		7365-45-9	230-907-9				
PENICILLIN- SREPTOMYCIN 005-589							
Gentamicin Sulfate		1405-41-0					
AMPHOTERICIN B		1397-89-3	215-742-2				

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	May cause irritation to mucous membranes. Move the exposed person to fresh air.
Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	May cause irritation to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion	May cause irritation to mucous membranes. DO NOT INDUCE VOMITING. Seek medical attention if irritation or symptoms persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area.

6.2. Environmental precautions

Do not allow product to enter drains. Prevent further spillage if safe.

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C. Keep containers tightly closed. Store in correctly labelled containers.

SECTION 8: Exposure controls/personal protection

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8.2. Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Wear protective clothing.
Eye / face protection	In case of splashing, wear:.. Approved safety goggles.
Skin protection - Handprotection	Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
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SECTION 10: Stability and reactivity

10.2. Chemical stability

	Stable under normal conditions.
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SECTION 11: Toxicological information

Further information

	No data is available on this product.
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SECTION 12: Ecological information

Further information

	No data is available on this product.
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SECTION 13: Disposal considerations

General information

	Dispose of in compliance with all local and national regulations.
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SECTION 14: Transport information

Further information

	The product is not classified as dangerous for carriage.
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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

	<p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p>
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Further information

	This SDS is prepared according to 29 CFR 1910.1200.
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SECTION 16: Other information

Other information

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Other information

Revision	This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
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Further information

	The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process.
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Bartels ViraTrans™

Viral Transport Medium

[REF]	B1029-35C	25 Vials
[REF]	B1029-35D	50 Vials

INTENDED USE

The **Bartels ViraTrans™ Transport Medium** is intended to stabilize viruses and suppress microbial contamination during transport of clinical specimens from the point of collection to the testing site. For *In Vitro* Diagnostic Use. Store at 2-8°C.

PRINCIPLE

Cell culture isolation is an important tool in the diagnosis of viral infections. A specimen is collected from the site of suspected infection and immediately placed into specialized transport medium formulated to maintain viability of any viruses present in the specimen and to suppress overgrowth of other microbial agents. Additionally, ViraTrans™ is non-inhibitory to cell culture, making it usable not only for transport but for cell culture inoculation. ViraTrans™ may also be used to prepare smears for direct patient testing. The specimen is transported on wet ice to the testing facility, where it is maintained at 2-8°C until it can be processed.

PRODUCT DESCRIPTION

ViraTrans™ - 2 ml of transport medium in a 15 ml conical centrifuge tube, allowing specimen collection, transport and processing in the same container. Medium contains Minimal Essential Medium with Hank's salts, fetal bovine serum, gentamicin, streptomycin, penicillin and amphotericin B, buffered with HEPES and sodium bicarbonate to a pH range of 7.0-7.8. Phenol red is added as a pH indicator. The transport tube also contains glass beads to aid in the disruption of patient's cells in the specimen with subsequent release of viruses into the medium. ViraTrans™ is available in a variety of packaging formats. Please contact Customer Service in the U.S. at 1-800-325-3424, or outside the U.S. at (353) 1 276 9800.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. ViraTrans™ should not be used beyond its expiration date.
3. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Decontamination is most effectively accomplished with a 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).

STABILITY AND STORAGE

Store at 2-8°C. The product retains potency until the expiration date shown on the label when stored properly.

QUALITY ASSURANCE

ViraTrans™ is tested for microbial contamination, toxicity to host cell culture and the ability to maintain viability of viruses. Quality assurance information is available upon request. Individual laboratories may evaluate the ability of ViraTrans™ to support viruses by *inoculating ViraTrans™* with appropriate stock cultures. After 72 hours at 2-8°C, using appropriate isolation procedures for viruses, positive growth should be obtained.

SPECIMEN COLLECTION

Proper specimen collection and handling are among the most important factors in successful detection of viruses. Use sterile cotton or DACRON® swabs with plastic or wire shafts, which are non-inhibitory to viruses. Do not use calcium alginate swabs.

AUTOPSY OR BIOPSY SPECIMEN

1. Collect fresh tissue from appropriate site using a separate sterile instrument to cut and remove each sample. Each specimen need not be more than 1-2 cm in diameter.
2. Place each sample into an individual leakproof container and cover with sufficient transport medium to prevent drying of specimen.
3. Tissue specimens should not be formalinized or fixed.

CEREBROSPINAL FLUID (CSF)

1. Collect cerebrospinal fluid in the usual manner.
2. Transfer up to 2 ml, equal to the amount of transport medium, into the vial.
3. If less than 1 ml of CSF is available, consult your laboratory for transport recommendations.

CERVIX

1. Remove exocervical mucus with swab and discard swab.
2. Insert fresh swab at least 1 cm into cervical canal, and rotate swab for 10 seconds.
3. Place swab into transport medium.

Note: For detection of HSV shedding, collection of a vulvar sample may increase recovery.

CUTANEOUS/VESICULAR LESION

1. Gently cleanse vesicle using a swab moistened with sterile saline.
2. Aspirate fluid with a tuberculin syringe or collect lanced vesicle onto a swab.
3. If vesicle is absent, vigorously swab base of lesion.
4. Transfer fluid or swab into transport medium.

EYE

1. Gently swab the lower conjunctiva with a sterile, finetipped swab, collecting patient mucous membrane cells.
2. Place swab into transport medium.

NASOPHARYNX

1. Gently insert a sterile nasopharyngeal swab into one or both anterior nares to the posterior pharynx, rotate to collect mucous membrane cells and withdraw.
2. Place swab into transport medium.

RECTAL SWAB

1. Insert a sterile swab 4-6 cm into rectum and roll swab against mucosa.
2. Place swab into transport medium.

RESPIRATORY ASPIRATE

(The quantity and quality of respiratory specimens to be tested can be improved by aspiration.)

1. Collect aspirates from nose, nasopharynx and/oropharynx.
2. Aspirates may be collected using a plastic disposable premature infant feeding tube attached to a 10 ml syringe. Alternately, a suction catheter with a mucous trap may be utilized.
3. Transfer up to 3 ml of aspirate into transport medium.

STOOL

1. Collect specimen in a clean, dry container.
2. Transfer sufficient faeces into transport medium to make a 20-40% suspension.

THROAT

1. Swab the posterior pharynx and tonsillar crypts vigorously with a large-tipped, sterile swab.
2. Place swab into transport medium.

URETHRA (Patient should not have urinated within one hour of collection)

1. Express and discard any exudate.
2. Insert flexible fine-shafted swab 2-4 cm into urethra.
3. Gently rotate swab two or three times, and withdraw.
4. Place swab into transport medium.

URINE

1. Collect a fresh, clean-catch specimen in a sterile container.
2. Transfer 2 ml into transport medium.

TRANSPORT AND STORAGE

After collection, store specimen tubes at 2-8°C. All collected specimens should be transported on wet ice to the laboratory immediately after collection. Specific requirements for shipping specimens should follow recommendations found in Titles 42 and 49 of the Code of Federal Regulations for interstate transport of etiologic agents. Failure to transport and store specimens at 2-8°C may lead to loss of viral infectivity. If the specimen cannot be processed within 3 days, freeze it at -70°C; however, freezing should be avoided if at all possible.

PROCESSING

If the transport tube contains a swab, it should be handled with sterile forceps. Rotate the swab in the transport medium, then press against the inside of the tube to allow excess fluid to drain back into the transport medium. If specimens are to be used for both direct detection and culture isolation/confirmation, half of the cells should be removed by centrifugation at 300 to 500xg and used for the direct specimen examination. Supernatant and remaining cells from the specimen should be used for processing specimens for cell culture isolation.

LIMITATIONS

1. Do **not** use ViraTrans™ if leakage, evaporation, pH change or signs of contamination are apparent.
2. Improper storage of ViraTrans™ may lead to decreased antibacterial and antimycotic activity.
3. Freezing of specimens should be avoided if possible; freezing may decrease recovery of viruses.
4. When performing a direct immunofluorescent test, **do not** freeze or vortex ViraTrans™ before slide preparation, as this can result in cellular disruption.

TECHNICAL INFORMATION

















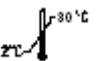



For further information or assistance, contact Technical Services.



WARNING: This product can expose you to chemicals including Streptomycin sulfate, which is known to the State of California to cause reproductive harm. For more information, go to www.P65Warnings.ca.gov.

ORDERING INFORMATION

KIT		Bartels Vira Trans Medium	
Catalog No.	Item	Quantity	
B1029-35C	Bartels Vira Trans Medium	25 Vials	
B1029-35D	Bartels Vira Trans Medium	50 vials	

 Manufactured	 High Pos or Positive Control
 Authorized Representative	 Low Pos or Cut-Off Control
 Consult accompanying documents	 Negative Control
 Product Number	 Calibrator
 Lot	 Coefficient Factor
 Use by	 Range
 Caution, consult accompanying documents	 Standard
 Store at 2-8°C	 For <i>In Vitro</i> Diagnostic use
 Store at 2-30°C	 or Hazard
 Trinity Biotech USA Jamestown, NY 14701 Tel. 1 800-325-3424 Fax: 716-488-1990	 Trinity Biotech plc Bray Co. Wicklow, Ireland Tel. 353 1 2769800 Fax 353 1 2769888 www.trinitybiotech.com
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