

SAFETY DATA SHEET (SDS)**IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER (1):**

Product Name: Kallestad™ HEp-2 Cell Line Substrate Slides

Product Number: 26100, 26101 (6 Wells/Slide)
26102, 26103, 26104 (12 Wells/Slide)
26105, 26106 (24 Wells/Slide)

Intended Use: These are replacement, optional or separately purchased component components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories **Kallestad™ HEp-2 Cell Line Substrate Test** kits. Refer to the *Instructions For Use, Package Insert* for additional product information.

Manufactured by: Bio-Rad Laboratories, Inc.

Address: 6565 185th Avenue NE
Redmond, WA 98052-5039, USA

Website: www.bio-rad.com

Phone Number: 1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)

SDS e-mail contact: ro-sds@bio-rad.com

Technical Information Contacts: Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2BIORAD (1-800-224-6723). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. Refer to section 16 for non-US local Bio-Rad agent contact information.

Authorized Representative in the European Community: **FRANCE:** Bio-Rad Laboratories
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92430 Marnes-la-Coquette
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[\[fds-msds.fr@bio-rad.com\]](mailto:fds-msds.fr@bio-rad.com)

Emergency Phone Number: This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product. Refer to section 16 for non-US local Bio-Rad agent contact information.

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (2):

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety. Refer to Section 16 for the full text of any *Risk (R)* and *Safety (S)* statement provided below.

Component *	Content
Hep-2 Substrate Slides 6 Wells/Slide - <i>Catalog # 26100, 26101</i> 12 Wells/Slide - <i>Catalog # 26102, 26103, 26104</i> <i>Optional Materials Available:</i> 24 Wells/Slide - <i>Catalog # 26105, 26106</i>	- HEp-2 substrate fixed onto glass slides - Handle slides by the edges. Do not apply pressure to surface of foil bag.

* Replacement, optional and separately purchased component Catalog numbers are provided in this column where available.

Markings according to the United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (HCS) and European Community (EC) 2008/1272/EC guidelines:

This product is not subject to labeling classification or identification according to GHS guidelines, United States Hazard Communication Standard (HCS) and EU 2008/1272/EC Regulations or other sources of literature known to us.

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COMPOSITION / INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data from the chemical raw material (LD₅₀, exposure limits, etc.) and that the product contains a significantly diluted concentration in an aqueous solution; thus, the assessment below has taken hazard reduction processing into consideration when possible. The GHS and EU classifications were made according to the latest editions and expanded upon from company and literature data. (Refer to the *Key* below.)

Chemical Ingredient: This product contains no chemical constituents that require regulatory control or disclosure at the concentration found in the product.

Biological Ingredient	Data / Information
HEp-2 Cell Line Slide Component	<p>HEp-2 cell (well characterized human epithelial cell line) substrate slides have been solvent fixed and are not considered infectious. Handle appropriately with the requisite Good Laboratory Practices and <i>Standard</i> and <i>Universal Precautions</i>. Dispose of this material in accordance with local, regional, national and international regulations.</p> <p>These slides consist of 96-100% inert glass with a ~0-4% inert polymer coating, which has been biologically and chemically processed. Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.</p>

Key:

- + The Kit Concentration was not tested; the values refer to the solution concentration as tested, designated by Percentage within parentheses.
- ++ The Kit Concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.
- NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified
- Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity
- GHS - Globally Harmonized System
- RTECS # - Registry of Toxic Effects of Chemical Substances number
- PEL - Permissible Exposure Limit / Occupational Exposure Limit (OEL)
- TLV/TWA - Threshold Limit Value / Time-Weighted Average
- STEL - Short Term Exposure Limit
- IDLH - Immediately Dangerous to Life or Health

Related product information:

- Refer to section 2 for the full text of any *GHS* /2008/1272/EC statement coded above. Refer to section 16 for the full text of any *Risk (R)* and *Safety (S)* statement for the above kit component concentration.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	No significant health effect is known. Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped.
Eye Contact:	OBTAIN MEDICAL ATTENTION.
Skin Contact:	Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
Inhalation:	No significant health effect is known.
If Swallowed:	OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician:	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

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FIREFIGHTING MEASURES (5):

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

ACCIDENTAL RELEASE MEASURES (6):

- ◆ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
- ◆ In the event of a hazardous material spill, contain the spill if it is safe to do so, and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. IF ON SKIN (or hair): Rinse skin with water. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- ◆ Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- ◆ Clean the spill area with water and wipe dry. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- ◆ Broken slides contaminated with blood or other human source or potentially infectious material must be handled as *Sharps* per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional, national and international regulations.
- ◆ Refer to Sections 8 and 13 for more specifics.

HANDLING AND STORAGE INFORMATION (7):

Handling:	This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard</i> and <i>Universal Precautions</i> . All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.
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Storage:	Store the kit components as specified on the product label and/or in the product instructions provided with the test kit.
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Caution, consult accompanying documents. Read and follow all the Precautions and Warnings in the kit product instructions.

These are separately purchased components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories kits listed in Section 1.

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

Control Parameters – Component chemicals with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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Additional information: The lists that were valid during the creation were used as basis.

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, and to prevent hazard inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

- Ventilation: Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material or patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
- Eye / Face Protection: Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
- Protective Gloves: Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.
- Protective Clothing: Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
- Respiratory Protection: Not required.
- Other: All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal.
- Note: Occupational exposure limit values and health hazard data were given in Section 3. Environmental controls are included in the following sections.

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Solid glass slides.		
Odour:	Data is not available.	Odour threshold:	Not established.
pH:	Not applicable.		
Boiling Point:	Not applicable.	Melting Point:	Not established
Flash Point:	Not applicable. Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u> .		
Evaporation rate:	Not applicable.		
Flammability (solid, gas):	Although the components have not been tested for fire hazard and explosion data, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor pressure:	Data is not available.		
Vapor density:	Data is not available.		
Relative density:	Not applicable.		
Solubility:	Not miscible.		
Partition coefficient (n-octanol/water):	Data is not available.		
Auto Igniting:	Product is not known to be self-igniting.		
Danger of Explosion:	Product is not known to present an explosion hazard.		
Decomposition temperature:	Data is not available.		

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Viscosity:	Data is not available.
No Other Standard Characteristics applicable to the identification or hazards of the product are known.	

STABILITY AND REACTIVITY INFORMATION (10):

NOTE: Chemical reactions that could result in a hazardous situation (e.g. generation of flammable or toxic chemicals, fire or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical Stability / Reactivity:	Stable under ordinary conditions of use and storage
Conditions and Materials to Avoid:	None known when used as intended.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Hazardous Polymerization:	Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Toxicity:	No significant toxic effect known.
Primary Irritant Effect:	No significant irritant effect known.
Serious Eye Damage / Irritation:	No significant irritant effect known.
STOT-Single Exposure:	Data is not available.
STOT-Repeated Exposure:	Data is not available.
Aspiration Hazard:	Data is not available.
Other Health Effects:	Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

Biohazard Potential:

Uninfected human cells have been solvent fixed and are not considered infectious or carcinogenic. Patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, *WHO Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization:	No sensitization effect known.
Carcinogenicity:	No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.
Germ Cell Mutagenicity:	Data is not available.
Reproductive hazard:	No reproductive toxic effect known.

ECOLOGICAL INFORMATION (12):

This product was not tested. The following assessment is based on information for the ingredients.

Toxicity:	No information found.
Persistence and degradability:	No information found.



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Bioaccumulation potential:	No information found.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse affects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional, national and international regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- Broken **slides** contaminated with blood or other human source or potentially infectious material must be handled as **Sharps** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional and national regulations.
- All **human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your national, regional and local ordinances accordingly.

Do not allow undiluted product or large quantities of it to reach ground water or water course

Recommended Unclean Packaging Disposal: Dispose in accordance with all applicable local, regional, national and international regulations.

TRANSPORT INFORMATION (14):

Shipping of product, packaging and waste must be conducted in accordance with all applicable local, regional, national and international regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health & Safety Office for your specific shipping procedures.

Recommended Unused Product Multi-Modal Transportation: According to US DOT, IATA and UN "Model Regulations", the product must be transported as follows: No known transport restrictions.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

REGULATORY INFORMATION (15):

Composite HMIS Rating: Health: 0 Flammability: 0 Reactivity: 0

California Proposition 65: The product does not contain listed substances.

Carcinogenicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA (Occupational Health and Safety Administration, U.S. Department of Labor).

National Regulations:

WHMIS Classification: This SDS contains the required information in accordance with the **Workplace Hazardous Materials Information System (WHMIS) Canadian Standard** for the hazard classification criteria for this product.

Mexican Standard: This SDS contains the required information for preparation in accordance with the **Mexican Standard (NMX-R-019-SCFI-2011) SISTEMA ARMONIZADO DE CLASIFICACIÓN Y COMUNICACIÓN DE PELIGROS DE LOS PRODUCTOS QUÍMICOS GLOBALLY HARMONIZED SYSTEM (GHS)**

Markings According to European Community 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC Guidelines: This product is not subject to EU labeling classification or identification according to EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC and other sources of literature known to us.

OTHER INFORMATION (16):

Risk Phrases: None

Safety Phrases: None

This product should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards.

Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

These are replacement, optional or separately purchased components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories kits listed in Section 1.

Sources of key data used to compile the Safety Data Sheet:

Raw Material Vendor Safety Data Sheets

United Nations (UN) Globally Harmonized System (GHS)

European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations

EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC

Registry of Toxic Effects of Chemical Substances (RTECS)

International Agency for Research on Cancer (IARC)

American Conference of Governmental Industrial Hygienists (ACGIH)

National Toxicity Program (NTP)

Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)

National Institute for Occupational Safety and Health (NIOSH)

World Health Organization. *Laboratory Biosafety Manual*

CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*

Mexican Standard (NMX-R-019-SCFI-2011)

California Proposition 65

Chemical safety assessment: Mixtures covered in this SDS were classified using the EU Regulation 1272/2008/EC and/or UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Fourth edition unless otherwise specified.

Key / legend to abbreviations and acronyms used in the safety data sheet:

ACGIH – American Conference of Governmental Industrial Hygienists

ANSI – American National Standards Institute

CAS – Chemical Abstracts Service

CDC – Centers for Disease Control, USA

CNS – Central Nervous System

DOT – Department of Transportation

EC₅₀ – half maximal effective concentration

EU – European Union

GHS – Globally Harmonized System

IATA – International Air Transport Association

IARC – International Agency for Research on Cancer

ICAO - International Civil Aviation Organization

IDLH – Immediately Dangerous to Life or Health

IMDG – International Maritime Dangerous Goods

IPCS – International Programme on Chemical Safety

LC₅₀ – median lethal concentration, 50%

LD₅₀ – median lethal dose, 50%

NIOSH – National Institute for Occupational Safety and Health

NTP – National Toxicity Program

OEL – Occupational Exposure Limit

PEL – Permissible Exposure Limit

ppm – parts per million

RTECS # – Registry of Toxic Effects of Chemical Substances number
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHO – World Health Organization (United Nations)

Additional information: The lists that were valid during the creation were used as basis.

This Revision: Updated, reformatted and added new GHS information..

Bio-Rad Laboratories:

Department issuing SDS: Environmental Health and Safety.

Contact for general SDS information: Redmond Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA, Phone: 425-881-8300 (8 am to 5 pm PT), ro-sds@bio-rad.com

Customer support contact: Clinical Diagnostics Group, 4000 Alfred Nobel Drive, Hercules, CA 94547, USA
Phone: 1-800-224-6723, www.bio-rad.com/diagnostics

Contact Local Bio-Rad Agents for general information:

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Israel, Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-3-9636050 • Telefax 972-3-9514129
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This document was developed from information obtained from reputable sources, but does not purport to be all-inclusive. The data contained herein, which is based on our present knowledge and is intended for information purposes only, shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Regulatory requirements are subject to change and vary from one location to another; thus, it is the buyer's responsibility to ensure that its activities comply with international, national, regional and local laws and regulations. Bio-Rad Laboratories makes no warranty, expressed or implied, regarding the accuracy or completeness of these data or the results to be obtained from the use thereof. Since the use of this information and the conditions of use of the product are not within the control of Bio-Rad Laboratories, it is the user's obligation to determine the suitability of the information for the intended application and use appropriate safety procedures.
