MATERIAL SAFETY DATA SHEET

HOLOGIC®

1. Product and Company Identification

Material name	**INVADER® FACTOR V; Invader® Factor V Intermediate, 144 tests; Invader® Factor V Controls, Intermediate; Invader® Factor V 1680 tests**
Revision date	7/9/12
Version #	101
CAS #	NA
Product code	95-453, 95-457, 89-0101, 89-0109
MSDS Number	LBL-01496
Manufacturer/Supplier	Hologic, Inc. 502 S. Rosa Road Madison, WI 53719-1256
Telephone number:	608-273-8933
Emergency	3E Hotline 1-866-519-4752 Access Code 333605

2. Hazards Identification

Physical state	Liquid.
Emergency overview	CAUTION May cause eye irritation.
OSHA regulatory status	This material is not considered hazardous by the OSHA Hazard Communication Standard, OSHA 29 CFR 1910.1200.
Potential health effects	
Routes of exposure	Eye contact. Skin.
Eyes	May cause eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort.
Skin	Prolonged contact may cause dryness of the skin.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Ingestion	Under normal conditions of intended use, this material does not pose a risk to health. However, ingestion may cause irritation and malaise.
Target organs	Eyes.
Chronic effects	No other specific acute or chronic health impact noted.
Signs and symptoms	Eye contact: Contact may cause irritation with redness, tearing and pain. High concentrations: Inhalation: Cough. May cause irritation to mucous membranes. Ingestion: May irritate and cause malaise.
Potential environmental effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Glycerol (component of Universal Enzyme Mix, PN 22-1717)	56-81-5	< 10

Composition comments	Box P/N 89-0101 contains tubes with the following names: Factor V Oligo Mix, PN 22-1859 Universal Buffer, PN 22-1716 Universal Enzyme Mix, PN 22-1717, and No DNA Control, PN 22-2000. Ingredients: Factor V Oligo Mix, PN 22-1859 None of the constituents of this mix are considered hazardous per US, Canadian, and EU rules and regulations. Ingredients: Universal Buffer, PN 22-1716 None of the constituents of this mix are considered hazardous per US, Canadian, and EU rules and regulations. Ingredients: Universal Enzyme Mix, PN 22-1717 This mix contains < 10% Glycerol. Ingredients: No DNA Control, PN 22-2000 None of the constituents of this mix are considered hazardous per US, Canadian, and EU rules and regulations. Box P/N 89-0109 contains tubes with the following names: G120a, G120b, G120c. None of the constituents of these mixes are considered hazardous per US, Canadian, and EU rules and regulations.

4. First Aid Measures

First aid procedures

Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. If irritation occurs, get medical assistance.
Skin contact	Wash contact areas with soap and water. Get medical attention if irritation develops or persists.
Inhalation	Move to fresh air. Get medical attention if any discomfort occurs.
Ingestion	Rinse mouth thoroughly with water and give large amounts of milk or water, if person is conscious. Never give anything by mouth to an unconscious person. Get medical attention if any discomfort continues.
Notes to physician	Treat symptomatically.
General advice	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties	The product is not flammable.
Extinguishing media	
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	No restrictions known.
Protection of firefighters	
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Fire fighting equipment/instructions	Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
Hazardous combustion products	Carbon oxides. Potassium chloride: During a fire, corrosive and toxic hydrogen chloride and/or chlorine gases, dipotassium oxide and other toxic and irritating fumes and gases may be formed by thermal decomposition.

6. Accidental Release Measures

Personal precautions	Avoid inhalation and contact with skin and eyes. Wear appropriate protective equipment and clothing during clean-up. See Section 8 of the MSDS for Personal Protective Equipment.
Environmental precautions	Prevent further leakage or spillage if safe to do so.
Methods for containment	Stop the flow of material, if this is without risk.

Methods for cleaning up Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal.

Never return spills to original containers for re-use.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling Avoid inhalation and contact with skin and eyes. Wear approved safety goggles. Observe good industrial hygiene practices.

Storage Store in closed original container in a dry place. Store away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	TWA	10 mg/m3	Mist.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	TWA	10 mg/m3	Mist.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	TWA	3 mg/m3	Respirable mist.
		10 mg/m3	Mist.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	TWA	10 mg/m3	Mist.

Canada. Quebec OELS. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	TWA	10 mg/m3	Mist.

Mexico. Occupational Exposure Limit Values

Components	Type	Value	Form
Glycerol (component of Universal Enzyme Mix, PN 22-1717) (56-81-5)	TWA	10 mg/m3	Mist.

Engineering controls Provide adequate ventilation. Observe occupational exposure limits and minimize the risk of inhalation of vapors and mist.

Personal protective equipment

Eye / face protection Wear approved safety goggles.

Skin protection For prolonged or repeated skin contact use suitable protective gloves. Risk of contact: Wear appropriate clothing to prevent repeated or prolonged skin contact.

Respiratory protection No protection is ordinarily required under normal conditions of use and with adequate ventilation. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not

been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 63 FR 1152, January 8, 1998. If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical & Chemical Properties

Appearance	Not available.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
Physical state	Liquid.
Form	Not available.
pH	Not available.
Melting point	Not available.
Freezing point	Not available.
Boiling point	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific gravity	Not available.
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	This product is stable under expected conditions of use.
Conditions to avoid	Freezing. Excessive heat. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Product	Test Results
INVADER® FACTOR V	Acute Other LD50 Mouse: 975.4139 mg/kg estimated

Acute effects	May cause eye irritation. Prolonged contact may cause dryness of the skin.
Local effects	Ingestion may cause irritation and malaise.
Sensitization	Not a skin sensitizer.
Chronic effects	No other specific acute or chronic health impact noted.
Carcinogenicity	Not classified.

Epidemiology	Not available.
Mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Neurological effects	Not available.
Reproductive effects	Contains no ingredient listed as toxic to reproduction.
Teratogenicity	Not available.
Symptoms and target organs	Eye contact: Contact may cause irritation with redness, tearing and pain. High concentrations: Inhalation: Cough. May cause irritation to mucous membranes. Ingestion: May irritate and cause malaise.
Further information	Not available.

12. Ecological Information

Ecotoxicological data

Product	Test Results
INVADER® FACTOR V	EC50 Daphnia: 12729.6981 mg/l 48 hours estimated

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Persistence and degradability	The degradability of the product has not been stated.
Bioaccumulation / Accumulation	No data available on bioaccumulation.
Partition coefficient (n-octanol/water)	Not available.
Mobility in environmental media	The product is soluble in water.

13. Disposal Considerations

Waste codes	Not regulated.
Disposal instructions	Disposal recommendations are based on material as supplied. Disposal must be in accordance with current applicable laws and regulations, and material characteristics at time of disposal.
Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

General	Factor V: Outer package is cardboard box containing 1 or 2 inner packages, which themselves contain various 2 ml and 0.5ml tubes

15. Regulatory Information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

TSCA Section 12(b) Export Notification(40 CFR 707, Subpt. D)

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
Section 302 extremely hazardous substance (40 CRF 355, Appendix A)	No
Section 311/312 (40 CFR 370)	No
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
WHMIS status	Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - Massachusetts RTK - Substance: Listed substance

Glycerol (component of Universal Enzyme Mix, PN 22-1717) (CAS 56-81-5) Listed.

US - New Jersey RTK - Substances: Listed substance

Glycerol (component of Universal Enzyme Mix, PN 22-1717) (CAS 56-81-5) Listed.

US - Pennsylvania RTK - Hazardous Substances: Listed substance

Glycerol (component of Universal Enzyme Mix, PN 22-1717) (CAS 56-81-5) Listed.

16. Other Information

HMIS® ratings	Health: 1* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 0 Instability: 0
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