1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier Trade name	invitrol Alkohol / Ammoniak Combi (L-1 and L-2)	
Relevant identified uses of	In vitro-Diagnostic Qualitäty control material	
Notes	The pharmacological, toxicological, and ecological properties of this product/ mixture have not been fully characterized. This data sheet will be updated as more data become available.	
Supplier	Company name	invicon diagnostic concepts GmbH
	Adress	Agnes-Pockels-Bogen 1 D-80992 München Germany
	World Wide Web	www.invicon.de
	Email	service@invicon.de
	Telefon	+49 89 319 047-0
	Telefax	+49 89 319 047-11
	invicon	+49 89 319 047-0
Emergency telephone number	invicon	Please use the local emergency telephon number
	Poison center	Please use the local poison center

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture	
Globally Harmonized System (GHS)	Respiratory sensitizer - Category 1. Skin sensitizer - Category 1.
Other/Supplemental Label elements	Mixture not yet fully tested.
GHS hazard pictogram	
GHS signal word	Danger (Gefahr)
GHS hazard statements	H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
CLP/GHS precautionary statements	P261 - Avoid breathing mist or vapor. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/face protection. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/ national/international regulations.
Other hazards	The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, were applicable. This product contains human source material (human serum albumin) and should be treated/handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance

	that these or other infectious agents are not present, this product should be handled using standard precautions. Because the mixture contains a protein, it may cause an allergic skin or respiratory reaction (e.g., potential to cause anaphylaxis). In a workplace setting, the likelihood of systemic effects following accidental ingestion is low, due to the rapid breakdown of proteins in the digestive tract.
Note	This mixture is classified as a hazardous according to Regulation EC No 1272/2008 (EU/CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	EU Classification	GHS Classification
Human serum albumin	70024-90-7	274-272-6	≤0.1 %	Harmful – Xn R42/43	RS1: H334; SS1: H317
2-Methyl-2H-isothiazol-3-one	2682-20-4	220-239-6	≤0.001 %	Corrosice – C: R34; R43; R37; R50	SC1: H314; ED1: H318; SS1: H317; STOT-SE3: H335; AA1: H400

Note	The ingredient(s) listed above are considered hazardous. Product also contains low levels of ethanol (0.07%).The remaining components are non-hazardous and/or present at amounts below reportable limits. See section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the CLP/GHS classification is based on Regulation (EC) 1272/2008.

4. FIRST AID MEASURES

Description of first aid measures	
Immediate Medical Attention Needed	Yes
Eye contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See sections 2 and 11
Indication of immediate medical attention and	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide and oxides of nitrogen.
Flammability/Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.

Advice for firefighters	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see section 8). Area should be adequately ventilated.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice with an appropriate solvent (see section 9).
Reference to other sections	See sections 8 and 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling	This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.
Conditions for safe storage including any incompatibilities	Store from at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.
Specific end use(s)	No information identified.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Note	Dispose of broken vials/syringes in a sharps container.

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Human serum albumin	--	--	--
2-Methyl-2H-isothiazol-3-one	--	--	--

Exposure/Engineering controls	Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.
Respiratory protection	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should be considered to provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Skin protection	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties	
Appearance	Liquid
Color	Clear.
Odor	No information identified.
Odor threshold	No information identified.
pH	6 - 8
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Miscible in water.
Solvent solubility	No information identified.
Partition coefficient (*n-octanol/water*)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular weight	No information identified.
Molecular formula	No information identified.

10. STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Avoid temperatures ≥ 25 °C.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects	
Route of entry	May be absorbed by inhalation, skin contact and ingestion.
Acute toxicity	

Compound	Type	Route	Species	Dose
Human serum albumin	--	--	--	--
2-Methyl-2H-isothiazol-3-one	--	--	--	--

Irritation/Corrosion	No studies identified.
Sensitization	No studies identified. As the Product/mixture contains material which is derivedfrom protein, there is potential for the mixture to cause an allergic response in humans.
STOT-single exposure	No studies identified.
STOT-repeated exposure/Repeat-dose toxicity	No studies identified.
Reproductive toxicity	No studies identified.
Developmental toxicity	No studies identified.
Genotoxicity	No studies identified.
Carcinogenicity	No studies identified. None of the components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data available.
Human health data	See "Section 2 - Other Hazards"
Additional information	The toxicological properties of this mixture have not been fully characterized.

12. ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Human serum albumin	--	--	--
2-Methyl-2H-isothiazol-3-one	LC_{50}/96h (5-chloro-2-methyl-4-isothiazolin-3-one)	Oncorhynchus mykiss (rainbow trout)	0.07 mg/L
	EC_{50}/48h (5-chloro-2-methyl-4-isothiazolin-3-one)	Daphnia magna (water flea)	0.18 mg/L

Persistence and Degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	No data available.
Other adverse effects	No data available.
Note	The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

14. TRANSPORT INFORMATION

Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.

Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Mixture not fully tested - avoid exposure.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Danger. May cause allergic respiratory reaction. May cause allergic skin reaction. Product contains human source material and should be treated/handled as a potential biohazard. Mixture not fully tested.
WHMIS classification	This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
TSCA status	Not listed.
SARA section 313	Not listed.
California proposition 65	Ethyl alcohol (ethanol) as contained in alcoholic beverages (and consumed) is listed as a reproductive toxicant, but this is not applicable with normal us of this product.

16. OTHER INFORMATION

Full text of R phrases and EU Classifications	Xn – Harmful. R42/43 Ma y cause sensitization by inhalation and skin contact. T+ - Very toxic. R28 – Very toxic if swallowed. R32 – Contact with acids liberates very toxic gas. N – Dangerous for the Environment. R50/53 – Very toxic to aquatic organisms, may cause long-therm adverse effects in the aquatic environment.
Full text of H phrases and GHS classification	ATO2 – Akute toxicity (oral) category 2. H300 – Fatal if swallowed. AA1 – Aquatic toxicity (acute) category 1 H400 – Very toxic to aquatic life. CA1 – Aquatic toxicity (chronic) category 1. H410 – Very toxic to aquatic life with long lasting effects. EUH032 – Contact with acids liberates very toxic gas. SS1 – Skin sensitizer category 1. H317 - May cause an allergic skin reaction. RS1 - Respiratory sensitizer category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled.
Sources of data	Information from published literature and internal company data.
Revisions	This is the second version of this SDS.
Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.