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

1.1 Product identifier	invitrol® Urin liquid	
Packaging types	invitrol® Urin liquid L-1 (15ml); invitrol® Urin liquid L-2 (15 ml); invitrol® Urin liquid Kombi (L-1+L-2, 15ml); invitrol® Urin liquid Kombi (L-1+L-2, 5ml);	REF 110211 REF 110212 REF 110213 REF 110201
1.2 Relevant identified uses of the substance or mixture and uses advised against	In vitro diagnostics for quality control	
1.3 Details of the supplier of the safety data sheet	Company name	invicon diagnostic concepts GmbH
	Street / P.O. Box	Floriansbogen 2-4
	Nation, postcode, city	Germany, 82061 Neuried
	Website	www.invicon.de
	Email address	service@invicon.de
	Telephone number	+49 89 319 047-0
	Fax	+49 89 319 047-11
1.4 Emergency telephone number	Company headquarters	+49 89 319 047-0 (Only available during office hours)
	Emergency number	Please call the regional poison centre

2. Hazards identification

2.1 Classification of the substance or mixture	
Regulation (EC) No 1272/2008 (GHS)	The mixture does not meet the criteria for classification in accordance with regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
2.2 Label elements	
Hazard pictograms (CLP/GHS)	Not required.
Signal word (CLP/GHS)	Caution.
Hazard statements (CLP/GHS)	H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP/GHS)	P273 - Avoid release to the environment. P501 - Dispose of contents/container in accordance with local/regional/national/ international regulations.
EU symbol/ hazard designation	Not required.
Risk phrases (R-phrases)	None.
Safety advice	None.

2.3 Other hazards

There are no known potential health hazards associated with exposure/handling of this mixture; no specific data are available for the mixture. The following data refer to the hazards of individual components, if applicable.

This product/mixture contains human material (human urine) and must be treated as a potential biohazard. All such human material was obtained exclusively from donors who were individually screened for antibodies to HIV and hepatitis B and C using FDA approved methods and no antibodies were detected. Nevertheless, the presence of these or other infectious agents cannot be excluded with absolute certainty. For this reason, standard biosafety precautions should be followed when handling this product

The mixture contains bovine serum albumin and may therefore cause allergic reactions of the skin or respiratory tract (e.g. anaphylaxis). In the workplace, the likelihood of systemic effects following accidental ingestion is low as proteins are rapidly broken down in the digestive tract.

Bovine serum albumin has been associated with occupational sensitisation. The material was manufactured in accordance with USDA and/or CPMP/BWP/1230/98 (Guidelines for minimising the risk of drug transmission of animal spongiform encephalopathy agents). This is Category IV material according to

	CPMP/BWP/1230/98: it does not contain specified risk materials as defined in Commission Decision 97/534/EC (or subsequent amendments) and is not derived from such materials.
2.4 Note	This mixture is classified as hazardous according to Directive 1999/45/EC, Regulation (EC) No 1272/2008 (EU CLP Regulation). The pharmacological, toxicological and ecological properties of this mixture have not been fully determined. The CLP/GHS classifications are based on Regulation (EC) No 1272/2008 and the revised OSHA Hazard Communication Standard. EU symbol / hazard designation, R-phrases and safety advice are based on Directive 1999/45/EC.

3. Composition / information on ingredients

3.1 Substances + 3.2 Mixtures

The above ingredients are classified as hazardous. Human urine is listed as it is potentially biohazardous. The product contains low concentrations of ethanol (≤ 0.02 %) as well as human serum albumin and active pharmaceutical ingredients (< 0.01 %). The remaining ingredients are not hazardous and/or are present in quantities below the reportable limit.

Name	***CAS-No.***	***EG-No.***	***Quantity***
Urin (human)	n.v.	n.v.	< 7.9%
Bovine serum albumin	9048-46-8	n.v.	≤ 0.06%
3:1-Mixture: 5-Chlor-2-methyl-4- isothiazoline-3-on + 2-methyl-4-isothiazoline-3-on	55965-84-9	613-167-00-5	≤ 0.02%

4. First aid measures

4.1 Description of first aid measures	
Immediate medical help required	Yes
After 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.
After skin contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
In case of inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is laboured, administer oxygen. Immediately notify medical personnel and supervisor.
After 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 responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
4.2 Most important symptoms and effects, both acute and delayed	See Sections 2 and 11
4.3 Indication of any immediate medical attention and special treatment needed	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

5. Firefighting measures

5.1 Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
5.2 Special hazards arising from the substance or mixture	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
5.3 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

6.1 Personal precautions, protective equipment and emergency procedures For non-emergency personnel	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.
6.2 Environmental precautions	Do not empty into drains. Avoid release to the environment.
6.3 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).
6.4 Reference to other sections	See Sections 8 and 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling	Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.
7.2 Conditions for safe storage, including any incompatibilities	Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.
7.3 Specific end use(s)	No information identified.

8. Exposure controls / personal protection

8.1 Control parameters	Contains no substances with occupational exposure limit values.
8.2 Exposure controls	Selection and use of containment equipment and personal protective equipment must be based on risk assessment of exposure potential. Use local exhaust ventilation and/or enclosed systems at aerosol/mist generating points. Emphasis should be placed on enclosed material handling systems and containment devices 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 provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or 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 a lower level of respiratory protection may not provide adequate protection.
Hand protection	Wear nitrile, rubber or other impervious gloves if skin contact is possible. If 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 and 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. Air and 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 safety 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

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

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties	
Physical state	Liquid
Colour	Colourless
Odour	No data available.
Melting point / freezing point	No data available
Boiling point and boiling range	No data available
Auto-ignition temperature	No data available
Lower and upper explosion limit	No data available
Flammability	No data available
Flash point	No data available
Decomposition temperature	No data available
pH value	5-8
Kinematic viscosity	No data available.
Solubility	Miscible in water
Partition coefficient n-octanol / water (log value)	No data available
Vapour pressure	No data available
Density and / or relative density	No data available.
Relative vapour density	No data available
Particle characteristics	No data available
9.2. Other information	None

10. Stability and reactivity

10.1 Reactivity	No data available
10.2 Chemical stability	Stable under recommended storage conditions
10.3 Possibility of hazardous reactions	No hazardous reaction when handled and stored according to provisions.
10.4 Conditions to avoid	Protect from heat and sunlight.
10.5 Incompatible materials	No data available
10.6 Hazardous decomposition products	No data available

11. Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008	
Intake	Can be inhaled, dermally and orally absorbed.
Acute toxicity	No data available
Skin corrosion / irritation	No data available
Sensitisation	No data available. As this product/mixture contains ingredients derived from proteins, it may cause allergic reactions in humans.
STOT-single exposure	No data available
STOT-repeated exposure	No data available
Reproductive toxicity	No data available

Developmental toxicity	No data available
Germ cell mutagenicity/Genotoxicity	No data available
Carcinogenicity	No studies conducted. None of the compounds in the mixture present at concentrations of at least 0.1% have been classified as carcinogenic by NTP, IARC, ACGIH or OSHA.
Aspiration hazard	No data available
Data on effects on human health	See 'Section 2 - Other hazards'.
11.2 Information on other hazards	The toxicological properties of this mixture have not been fully determined.

12. Ecological information

12.1 Toxicity

Compound	*Type*	*Species*	*Concentration*
Urine (human)	--	--	--
Bovine serum albumin	--	--	--
5-Chlor-2-methyl-4-isothiazoline-3-on	EC50/96 h	Pseudokirchneriella subcapitata (Alge)	0.03 – 0.13 mg/l
	EC50/48 h	Daphnia magna	4.71 mg/l
	LC50/96 h	Oncorhynchus mykiss	1.6 mg/l
2-Methyl-4-isothiazoline-3-on	--	--	--

12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in soil	No data available
12.5 Results of PBT and vPvB assessment	No data available
12.7 Other adverse effects	No data available
12.8 Note	The environmental properties of this product/mixture have not been fully investigated. Avoid release to the environment.

13. Disposal considerations

13.1 Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner.

14. Transport information

14.1 UN number	None assigned.
14.2 UN proper shipping name	None assigned.
14.3 Transport hazard classes and packing group	None assigned.
14.4. Packing group	None assigned.
14.5 Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
14.6 Special precautions for users	Mixture not fully tested - avoid exposure.
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	Not applicable.

15. Regulatory information

15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under current guidelines in the EU. Consult your local or regional authorities for more information.
15.2 Chemical safety assessment	For this mixture, a chemical safety assessment is not required

16. Other information

16.1 Change from the last version	New address, Chap. 1.3
16.2 Abbreviations	CAS Chemical Abstract Service Registry Number CLP Classification, Labelling and Packaging EC50 Median effective concentration: The concentration of a substance at which 50% of the maximum biological effect is achieved EG Classification category of European chemicals law (REACH regulation) GHS Globally Harmonized System for Classification and Labeling of Chemicals GKV Österreichische Grenzwerteverordnung (Austrian Limit Values Ordinance) KZW Short-term value (limit value for short-term exposure): Limit value that should not be exceeded, based on a period of 15 minutes LC50 Median lethal concentration: The concentration of a substance in the air or water that causes death in 50% of the test organisms within a certain period of time. Refers to exposure to a medium such as air or water LD50 Median lethal dose: The dose of a substance that causes death in 50% of the test organisms within a certain period of time. Refers to the ingestion of the substance SMW Shift average (limit value for long-term exposure): Time-weighted average, measured or calculated for a reference period of eight hours SUVA Schweizerische Unfallversicherungsanstalt (Swiss Accident Insurance Fund) TRGS Technische Regeln für Gefahrstoffe (Technical rules for hazardous substances) VwVwS Administrative regulations for substances hazardous to water
16.3 Sources of data	Information from published literature and internal company data.
16.4 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. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.