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

1.1 Product identifier	invitrol® Urin dipStick	
Packaging types	invitrol® Urin dipStick Kombi (L-1+L-2), invitrol® Urin dipStick L-1, invitrol® Urin dipStick L-2,	REF 110223 REF 110226 REF 110227
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	
Verordnung (EG) Nr. 1272/2008 (GHS)	Respiratory sensitisation - Category 1. Skin sensitisation - Category 1. The mixture has not yet been fully tested.
Richtlinie 67/548/EWG oder 1999/45/EG	Xn - R42 (Respiratory sens.), R43 (Skin sens.). The mixture has not yet been fully analysed.
2.2 Label elements	
Hazard pictograms (CLP/GHS)	
Signal word (CLP/GHS)	Danger
Hazard statements (CLP/GHS)	H317 - May cause an allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements (CLP/GHS)	P261 - Avoid breathing mist or aerosol. P272 - Do not wear contaminated work clothing outside the workplace. P280 - Wear protective gloves/eye protection/face protection. P285 - Wear respiratory protection if ventilation is inadequate. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - If inhaled: If breathing is difficult, remove 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 respiratory symptoms occur: Call a poison centre or doctor. P363 - Wash contaminated clothing before reuse. 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 a protein (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 ingredients below are classified as hazardous. Human urine is listed as it is potentially biohazardous. The product also contains traces of 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.	<9 %
Dimethylsulfoxide	67-68-5	200-664-3	<1.4 %
Bovine serum albumin	9048-46-8	n.v.	<0.9 %
Sulfobromophthaleine-sodium salt	71-67-0	200-761-0	≤ 0.1%
3:1-Mixture: 5-Chlor-2-methyl-4- isothiazoline-3-on + 2-methyl-4-isothiazoline-3-on	55965-84-9	613-167-00-5	≤ 0.006 %

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

Compound	Herausgeber	SMW	KZW
Dimethyl sulfoxide	AT (GKV)	160	--
	CH (SUVA)	160	320
	DE (TRGS 900)	160	320

SMW: Shift average (limit value for long-term exposure): Time-weighted average, measured or calculated for a reference period of eight hours
KZW: Short-term value (limit value for short-term exposure): Limit value that should not be exceeded, based on a period of 15 minutes

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 up to yellowish
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

Compound	*End point*	*Intake*	*Species*	*Dosage (g/kg)*
Urine (human)	--	--	--	--
Dimethyl sulfoxide	LD50	Oral	Rat	28,3
	LD50	Oral	Mouse	21,4
Bovine serum albumin	--	--	--	--
Sulfobromophthaleine-sodium salt	LD50	Intravenous	Mouse	0,334
3:1-Mixture: 5-Chlor-2-methyl-4- isothiazolin-3-on + 2-methyl-4-isothiazolin- 3-on	--	--	--	--

Skin corrosion / irritation: No data on product formulation available. Dimethyl sulfoxide is a skin irritant in humans and animals.

Sensitisation: No data on product formulation available. Bovine serum is derived from animal material (foreign material) and therefore the material may cause allergic reactions in humans. Occupational exposure to bovine serum has caused some cases of allergic sensitisation in people working with this material.

STOT-single exposure: No data on product formulation available. Male rats were exposed to an aerosol of 1600 mg/m3 DMSO for 4 hours. One group was killed immediately after exposure, the second 24 hours after exposure. The third group was observed for 2 weeks after exposure before being killed. No mortality occurred and none of the animals showed external signs of toxicity during and after exposure to DMSO. The organs were normal at necropsy.
Groups of male and female rats were given single intravenous injections of undiluted DMSO. The dose levels were 2.5, 5 and 10 g/kg. Each dose was administered over a period of 1 minute. The animals were observed for 14 days after DMSO administration. With one exception, deaths occurred within the first 24 hours. Non-lethal doses of DMSO resulted in reduced motor activity and myasthenia.

STOT-repeated exposure: No data on product formulation available. Male rats were exposed to 200 mg/m3 DMSO for 7 hours on 5 days per week over a period of 6 weeks (30 exposures). There were no external toxic signs in the exposed animals during the experimental period of 6 weeks and no effects on blood parameters were reported.
DMSO was administered dermally to rabbits at a dose of 1 or 5 g/kg/day for 30 days. The rabbits received dermal applications of DMSO on normal and abraded skin for a period of 23 weeks during which ocular changes were observed. Treatment was discontinued in animals with ocular changes. The remaining animals continued to receive DMSO applications for the planned 26 weeks (6 months). Mortality was high in all groups, but there were no significant differences between the groups. There were no clinical signs suggestive of systemic toxicity.
DMSO was administered to rhesus monkeys as a 90% solution by gavage 7 days per week for 87 weeks. The doses were 990, 2970 and 8910 mg/kg/day. The main

	physical symptoms of the animals given DMSO orally included increased salivation and vomiting. These symptoms occurred sporadically and did not appear to be related to dosage except in the group receiving a higher volume of the compound. Anorexia occurred at high oral doses but was not evident at the 2 lower doses. No DMSO-related changes were noted in the treated monkeys during physical examinations.
Reproductive toxicity	No data on product formulation available. DMSO has been widely used as an antifreeze in the freezing of early experimental animal and human embryos. The viability and apparent normality of frozen embryos after thawing suggest that DMSO is not toxic to early embryos.
Developmental toxicity	No data on product formulation available. Inconclusive: DMSO at high doses has been associated with teratogenic and/or embryotoxic effects in hamsters, rats, mice and chicks. In hamsters, injection of 500 to 800 mg/kg on day 8 of gestation resulted in a variety of congenital defects, such as exencephaly, microphthalmia, bone and limb malformations and cleft lip. An increased foetal death rate was observed when pregnant rats and rabbits were administered a dose of 5-10 and 1-3 g/kg/day respectively. However, in another study, no increased foetal death rate was observed after intraperitoneal treatment of pregnant rats with 6.9 g/kg/day dimethyl sulphoxide. No malformations were observed in the offspring of rats treated with dimethyl sulphoxide at doses of 0.2-5 g/kg/day during gestation.
Germ cell mutagenicity/Genotoxicity	No data on product formulation available. A mutagenicity test according to Ames and a sister chromatid exchange test with Chinese hamster eggs did not reveal any genotoxicity of dimethyl sulphoxide.
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)	--	--	--
Dimethyl sulfoxide	EC_{50}/424 h LC_{50}/96 h	Daphnia magna Oncorhynchus mykiss	7 g/l 33–37 g/l (statisch)
Bovine serum albumin	--	--	--
Sulfobromophthaleine-sodium salt	--	--	--
5-Chlor-2-methyl-4-isothiazoline-3-on	EC_{50}/96 h	Pseudokirchneriella subcapitata (Alge)	0,03 – 0,13 mg/l
2-Methyl-2H-isothiazole-3-on	EC_{50}/48 h LC_{50}/96 h	Daphnia magna Oncorhynchus mykiss	4,71 mg/l 1,6 mg/l

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.