
	<b>Safety Data Sheet</b> According to Regulation (EC) No. 1907 / 2006 (REACH)		
	<b>invitrol Drugs</b>		
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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier	invitrol Drugs	
Trade name	(in different versions: L-1, L-2, L-3, L-4, L-5, L-6)	
Relevant identified uses of The substance or mixture and uses advised against	In vitro-diagnostic quality control material	
Note	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 telephone number
	Poison center	Please use the local poison center

## 2. HAZARDS IDENTIFICATION

Classification of the substance or mixture	
Regulation (EC) no 1272/2008 (GHS)	Respiratory Sensitizer - Category 1. Skin Sensitizer - Category 1. Mixture not yet fully tested.
Directive 67/548/EWG or 1999/45/EC	Xn - R42 (Respiratory Sens.), R43 (Skin Sens.). Mixture not yet fully tested.
CLP/GHS hazard pictogram	
CLP/GHS signal word	Danger (Gefahr)
CLP/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.
Risk (R) Phrase(s)	R42/43 - May cause sensitization by inhalation and skin contact.
Safety Advice	S2 - Keep out of reach of children. S23 - Do not breathe spray. S24 - Avoid contact with skin. S37 - Wear suitable protective gloves. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

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**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, where applicable.

This product contains human urine and should be treated/handled as a potential biohazard. All such human urine 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 biosafety precautions.

Because the mixture contains bovine serum, 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. Bovine serum albumin has been associated with occupational sensitization. Material produced in compliance with USDA and/or CPMP/BWP/1230/98 (Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/ BWP/1230/98 Category IV material: it does not contain nor is it derived from specified risk materials as defined in Commission decision 97/534/EC (or successive amendments).

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Ingredient	CAS #	EINECS/ELIN CS#	Amount	EU Classification	GHS Classification
Urine Human	N/A	N/A	>5%	Not classified	Not classified
Bovine serum albumin	9048-46-8	N/A	1-2 %	Harmful – Xn: R42/R43	SS1: H317 RS1: H334
Sodium azide	26628-22-8	247-852-1	0.05-0.099%	Very Toxic – T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400, CA1: H410 EUH032

**Note**

The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product also contains trace (0.001%-0.008%) amounts of various active pharmaceutical ingredients, and trace levels of ethanol. 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 Special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

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**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 toxic gases of 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). Disinfect the area twice with an appropriate solvent, such as 5% chlorine bleach solution.
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 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			
<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Urine (Human)	--	--	--
Bovine serum albumin	--	--	--
Sodium azide	ACGIH	OEL-STEL	0,3 mg/m <sup>3</sup>
	Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus; Czech Republic, Estonia Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	--	--
	New Zealand, Portugal	Ceiling	0.29 mg/m <sup>3</sup>

Sodium azide	ACGIH Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus; Czech Republic, Estonia Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-TWA	0.1 mg/m <sup>3</sup>
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m <sup>3</sup>
	Germany	OEL-STEL	0.4 mg/m <sup>3</sup>
	Germany	OEL-TWA	0.2 mg/m <sup>3</sup>
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 provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.		
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/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 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	Clear liquid
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	5 – 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 ( <i>n</i> -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.			
<b>10. STABILITY AND REACTIVITY</b>				
Reactivity	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.			
Chemical stability	Stable when stored as recommended.			
Possibility of hazardous reactions	Not expected to occur.			
Conditions to avoid	Avoid temperatures $\geq 25$ °C; excess heat.			
Incompatible materials	No information identified.			
Hazardous decomposition products	No information identified.			
<b>11. TOXICOLOGICAL INFORMATION</b>				
Information on toxicological effects				
Route of entry	May be absorbed by inhalation, skin contact and ingestion			
Acute toxicity				
<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Urine ( Human)	--	--	--	--
Bovine serum albumin	--	--	--	--
Sodium azide	LD <sub>50</sub>	Oral	Rat	27 mg/kg
	LD <sub>50</sub>	Oral	Mouse	27 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	20 mg/kg
Additional acute toxicity information	No studies identified.			
Irritation/Corrosion	No studies identified.			
Sensitization	No studies identified. As bovine serum albumin (BSA) is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans. Occupational exposure to BSA has caused some cases of allergic sensitization in workers handling this material.			
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. This mixture is not 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
Urine (Human)	--	--	--
Bovine serum albumin	--	--	--
Sodium azide	LC <sub>50</sub> /96h	Oncorhynchus mykiss	0.8 mg/L
	LC <sub>50</sub> /96h	Lepomis macrochirus	0.7 mg/L
	LC <sub>50</sub> /96h	Pimephales promelas	5.46 mg/L

Additional toxicity information Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal pipping as it has the potential to form explosive mixtures.

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. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. 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 Yes. Danger. May cause allergic respiratory reaction. May cause allergic skin reaction. Product contains human urine 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 use of this product.

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**16. OTHER INFORMATION**

Full text of R phrases and EU Classifications Xn - Harmful.  
R42 - May cause sensitization by inhalation.  
R43 - May cause sensitization by 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-term adverse effects in the aquatic environment.

Full text of H phrases, P phrases and GHS classification 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.  
ATO2 - Acute Toxicity (Oral) Category 2.  
H300 - Fatal if swallowed.  
AA1 - Aquatic toxicity (acute) Category 1.  
H400 - Very toxic to aquatic life.  
CA1 - Chronic Aquatic Toxicity Category 1.  
H410 - Very toxic to aquatic life with long lasting effects.  
EUH032 - Contact with acids liberates very toxic gas.

Sources of data Information from published literature and internal company data.

Revisions This is the first 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. 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 result 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 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.