

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

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General



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Product identifier

Brevital® (Methohexital) Sodium for Injection (lyophilized powder)

Synonyms

For methohexital sodium: Barbituric acid, 5-allyl-1-methyl-5-(1-methyl-2-pentynyl), sodium salt; Brietal sodium; Enallnynal sodium

Trade names

Brevital®

Chemical family

Mixture containing a barbituate

Relevant identified uses of the substance or mixture and uses advised against

Bulk formulated pharmaceutical mixture/formulated pharmaceutical product packaged in final form for patient use; indicated for use as a general anesthetic.

Note

The physical, chemical, toxicological and ecological properties of this product/mixture has not been fully characterized. This SDS will be revisited as more data become available.

Issue Date

30 September 2014

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Please consult the prescribing/packaging information. **The classification and labeling listed below is for bulk Brevital® (methohexital) sodium for injection.**

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Regulation (EC) 1272/2008 [GHS] Corrosive (skin) - Category 1. Corrosive (eye) - Category 1. Specific Target Organ Toxicity (single exposure) - Category 3.

Directive 67/548/EEC or 1999/45/EC C - R35; R67

Label elements

CLP/GHS hazard pictogram



CLP/GHS signal word

Danger

CLP/GHS hazard statements

H314 - Causes severe skin burns and eye damage. H336 - May cause drowsiness or dizziness.

CLP/GHS precautionary statements

P260 - Do not breathe dust. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves/eye protection/face protection. P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 - If on skin or hair: Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a Poison Center or doctor/physician. P321 - Specific treatment (see First Aid information on product label and/or Section 4 of the SDS). P363 - Wash contaminated clothing before reuse. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger



C - Corrosive

Risk (R) Phrase(s)

R35 - Causes severe burns. R67 - Vapors may cause drowsiness and dizziness.

Safety Advice

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection. S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Other hazards

Methohexital sodium ("methohexital") is an ultra-fast-acting general anesthetic. It is usually administered by intravenously (IV) or intramuscularly (IM) at typical total doses of 50-120 mg (given at a rate of 2 mg/sec). Sleep induction occurs almost immediately following IV injection, and within about 2-10 minutes of IM administration. Adverse effects generally correspond to central nervous system (CNS) depression (the desired pharmacological effect) and may include respiratory effects (*e.g.*, depression, shortness of breath, and laryngo/bronchospasm), cardiovascular effects (*e.g.*, hypotension and tachycardia), gastrointestinal disturbances, anxiety, delirium, muscle twitches, and seizures. Prolonged administration may cause extended drowsiness and protracted unconsciousness. Overdosage may lead to exacerbated CNS effects, including cardiac arrest and/or death.

Methohexital is a U.S. DEA Schedule IV Controlled substance, with a slight potential for dependence/abuse. Like most general anesthetics, methohexital readily crosses the placental barrier and may directly affect a developing fetus.

US Signal word

Danger

US Hazard overview

Contains sodium hydroxide (a corrosive) and methohexital sodium (a barbituate). Causes severe eye/skin burns. May cause drowsiness or dizziness.

Note

This mixture is classified as dangerous/hazardous according to directive 1999/45/EC, Regulation (EC) No 1272/2008 (EU CLP) and applicable US regulations. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. The GHS classifications are based on Regulation (EC) 1272/2008. See Section 16 for full text of EU and GHS classifications.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Methohexital sodium	309-36-4	206-217-9	70 - 85%	R67	STOT-S3: H336
Sodium Hydroxide	1310-73-2	215-185-5	5 - 10%	C: R35	SC1: H314

Note

The ingredient(s) listed above are considered dangerous/hazardous. The remaining components are non-dangerous/not 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 GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

SECTION 4 - FIRST AID MEASURES ...continued

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	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	Contains sodium hydroxide (a corrosive material) and methohexital sodium (a barbituate). Medical conditions aggravated by exposure: cardiovascular, respiratory, or CNS disorders. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking other medication(s), consult the corresponding package or prescribing information for potential drug interactions.

SECTION 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 fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, phosphate and any sodium-containing compounds.
Flammability/Explosivity	No specific information identified for the product/mixture. High concentrations of finely divided airborne particles can potentially explode if ignited.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 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. Do not breathe dust.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	If vials are crushed or broken, DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for 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.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	If vials are crushed or broken, follow recommendations for handling potent pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling.
Conditions for safe storage including any incompatibilities	Store at controlled room temperature 22 to 25°C (68 to 77°F), away from incompatible materials. Protect from light and moisture. Product is oxygen sensitive.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note	Wash hands, face and other potentially exposed areas immediately in the event of physical contact. Dispose of broken vials in a sharps container.
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SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

**Control Parameters/
Occupational Exposure
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Methohexital sodium	--	--	--
Sodium Hydroxide	ACGIH, Czech Republic, Denmark, Finland, NIOSH, Portugal, Spain, Sweden, Australia, Mexico	Ceiling	2 mg/m ³
	Austria, Belgium, Bulgaria, Finland, France, Hungary, Lithuania, Slovak Republic, Slovenia, Spain, OSHA	TWA-8 HR	2 mg/m ³
	Austria	STEL (8 x 5 min)	4 mg/m ³
	Czech Republic, Estonia, Sweden	TWA-8 HR	1 mg/m ³
	Hungary, Ireland, Slovenia, Singapore	STEL	2 mg/m ³
	Latvia, Poland	TWA-8 HR	0.5 mg/m ³
	NIOSH	IDLH	10 mg/m ³
	Poland	STEL	1 mg/m ³

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

Exposure/Engineering controls	None required for normal handling of packaged product. If vials are crushed/broken or if handling bulk mixture: Control exposures to below the OEL for the active pharmaceutical ingredient (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.
Respiratory protection	None required for normal handling of packaged product. If vials are crushed/broken or if handling bulk mixture: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should 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	None required for normal handling of packaged product. If vials are crushed/broken or if handling bulk mixture: 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. 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 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).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Appearance	Lyophilized powder
Color	White to off-white
Odor	Odorless
Odor threshold	No information identified.
pH	10-11 (as a 1% solution)
Melting point/ freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	Not applicable.
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	Soluble.
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	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Light sensitive
Possibility of hazardous reactions	No information identified.
Conditions to avoid	Avoid extreme temperatures.
Incompatible materials	Strong oxidizers.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note	No toxicology data for the product/mixture were identified. The following data describe the active ingredient and/or the individual ingredients where applicable.
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Information on toxicological effects

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

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Methohexital sodium	LD ₅₀	Intravenous	Rat	25 mg/kg
	LD ₅₀	Intravenous	Rabbit	8.6 mg/kg
	LD ₅₀	Intravenous	Mouse	35.6 mg/kg
Sodium Hydroxide	--	--	--	--

Irritation/Corrosion	Sodium hydroxide is corrosive to the eye and skin <i>in vitro</i> and <i>in vivo</i> .
Sensitization	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure/Repeat-dose toxicity	No data available.
Reproductive toxicity	Methohexital did not impair fertility in reproduction studies animals (details not specified).
Developmental toxicity	Methohexital was not developmentally toxic to rats and rabbits treated with doses up to 4 and 7 times the typical human dose, respectively. No details were specified.
Genotoxicity	Methohexital was negative for genotoxicity in the Ames bacterial mutagenicity assay.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Carcinogenicity	No studies identified. None of the components of this 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"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Methohexital sodium	--	--	--
Sodium Hydroxide	Toxic range	freshwater fish and invertebrates	20 to 40 mg/L (data on pH changes unavailable)

Persistence and Degradability Sodium hydroxide rapidly dissolves and dissociates in water. No data were available for other ingredients.

Bioaccumulative potential No data identified.

Mobility in soil No data identified.

Results of PBT and vPvB assessment Not performed.

Other adverse effects No data identified.

Note Aquatic toxicity of sodium hydroxide is related to the effects of pH changes. Sodium hydroxide in neutralized mixtures is not considered toxic to the environment. Because data on other ingredients were not identified, releases into the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. 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.

SECTION 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	Avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 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/regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Yes. Causes severe eye/skin burns. May cause drowsiness or dizziness.
WHMIS classification	Not required. Drugs are not subject to WHMIS. 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. If this product/mixture were not a drug, it would be classified as: Class E - Corrosive Material
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	C - Corrosive. R35 - Causes severe burns. R67 - Vapors may cause drowsiness and dizziness.
Full text of H phrases, P phrases and GHS classification	SC1 - Skin corrosion Category 1. H314 - Causes severe skin burns and eye damage. STOT-S3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H336 - May cause drowsiness or dizziness.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Revisions	This is the first version of this SDS.
Disclaimer	<p>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.</p> <p>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 potent pharmaceutical 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.</p>