	SPECIFICATION	SPC 00314	4.0
cerus	Safety Data Sheet (SDS): Amotosalen Hydrochloride Solution		

SECTION 1: Identification

Contact information

General

For North America, Latin America, Asia:
Cerus Corporation
1220 Concord Avenue,
Suite 600
Concord, CA 94520 USA
E-mail: EHS@cerus.com Main: +1 (925) 288-6000 (Available 8am-5pm Pacific Time)

For Europe:
Cerus B.V.
Stationsstraat 79-D, 3811 MH Amersfoort, The Netherlands
E-mail: EHS@cerus.com Phone: +31 33 496 0600 (Available 8am-5pm Central European Time)

Emergency telephone number

Chemtrec (24-hour availability):
+1 (800) 424-9300 (USA and Canada)
+1 (703) 527-3887 (International; collect calls accepted)

Product identifier	Amotosalen Hydrochloride solution
Synonyms	3-[2-Aminoethoxy)methyl]-2,5,9-trimethyl-7H-furo[3,2-g][1]benzopyran-7-one hydrochloride; S-59; Amotosalen HCl – Solution; Amotosalen solution
Trade name	Not applicable
Chemical family	Mixture – Amotosalen Hydrochloride in 0.9% Saline (3 mM and 6 mM)
Recommended uses and restrictions	Amotosalen hydrochloride solution pouches packaged with INTERCEPT™ Blood System processing sets are used for the inactivation of viruses, bacteria, and leukocytes in human platelets and plasma.
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the product in a blood bank or equivalent working environment. The physical, chemical, and ecological properties of this product/ mixture have not been fully characterized. This SDS will be revisited as more data become available.

SECTION 2: Hazard(s) identification

Classification of the substance or mixture

The classification and labeling listed below is for amotosalen hydrochloride solution .

Not classified

Label elements

GHS Hazard pictograms	Not applicable
GHS Signal word	Not applicable
GHS Hazard statements	Not applicable
GHS Precautionary statements	Not applicable

Other hazards

Amotosalen hydrochloride solution is used as a photochemical treatment process as part of the INTERCEPT™ Blood System for the inactivation of viruses, bacteria, and leukocytes in platelets and plasma used by patients requiring intravenous transfusions. Amotosalen reversibly binds to nucleic acids; following activation by UVA, it forms irreversible adducts and crosslinks with RNA and DNA, blocking replication.

Skin contact may result in photosensitization in the presence of UVA.

Note This mixture does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it has not yet been fully tested and is pharmacologically active.

SECTION 3: Composition/Information on ingredients

Ingredient	CAS number	EINECS/ELINCS#	Amount	GHS classification
Amotosalen HCl	161262-45-9	N/A	0.1 – 0.2 %	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1B, H317

Note The ingredients listed above are considered hazardous. Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. The remaining components are not hazardous and/or are present in formulation at amounts below reportable limits. The primary ingredient in this mixture is sterile water. See Section 16 for full text of GHS classifications.

SECTION 4: First-aid measures

Description of first aid measures

Immediate medical attention and special treatment, if necessary No. If exposed or concerned, get medical advice/attention.

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.

Skin contact Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

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.

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.

Most Important Symptoms/Effects Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

Expected Symptoms/Effects, Acute and Delayed See Sections 2 and 11.

SECTION 5: Fire-fighting measures

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and chlorine, and other nitrogen- and chlorine-containing compounds.

Fire hazard No information identified. As product is an aqueous solution, it is not expected to be flammable.

Explosion hazard No information identified. As product is an aqueous solution, it is not expected to be explosive.

Special protective equipment and precautions for fire-fighters

Firefighting instructions 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.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Protective equipment — 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.

Emergency procedures — Do not breathe vapors/mist/spray.

Environmental precautions — Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up

Methods for cleaning up — If pouches are damaged or broken, 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).

Other information — Dispose of materials or solid residues at an authorized site.

Reference to other sections — See Sections 8 and 13 for more information.

SECTION 7: Handling and storage

Precautions for safe handling — If pouches are damaged or broken, solution may be released. Follow recommendations for handling bulk formulated/packaged biochemical reagents (i.e, use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin, and other mucous membranes. Wash thoroughly after handling. Do not breathe vapors/mist/spray.

Conditions for safe storage, including any incompatibilities

Storage conditions — Follow INTERCEPT™ Blood System for Platelets and INTERCEPT™ Blood System for Plasma labelling instructions for storage and handling.

Storage temperature — Below 25 °C; do not freeze

Specific end use(s) — Medical device. Used to inactivate pathogens such as viruses, protozoa, and bacteria in human blood products.

SECTION 8: Exposure controls/personal protection

Note — Wash hands, face, and other potentially exposed areas immediately in the event of physical contact.

Control parameters/Occupational Exposure Limits

Name	Issuer	Value
Amotosalen HCl	Cerus Corp.	70 µg/m³

Appropriate engineering controls — None required for normal handling of packaged product. If pouches are damaged or broken, or if handling bulk formulation: 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. Use engineered local exhaust ventilation (LEV) and/or enclosure for procedures where aerosolization may occur such as opened transfers, pumping, and spraying. Solutions can be handled outside a containment system or without LEV during procedures with no potential for aerosolization. All containers for solutions and slurries must be covered while being transferred

Respiratory protection — None required for normal handling of packaged product. If pouches are damaged or broken, or if handling bulk formulation: choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should be considered based on the known or foreseeable limitations of existing engineering controls.

Hand protection — None required for normal handling of packaged product. If pouches are damaged or broken, or if handling bulk formulation: Wear nitrile or other impervious gloves if skin contact is possible. When the material is diluted in an organic solvent, wear gloves that provide protection against the solvent.

Eye protection	None required for normal handling of packaged product. If pouches are damaged or broken, or if handling bulk formulation: 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.
Skin and body protection	None required for normal handling of packaged product. If pouches are damaged or broken, or if handling bulk formulation: Wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices
Other protective measures	Wash hands in the event of contact with product 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).
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.

SECTION 9: Physical and chemical properties

Physical state	Liquid in plastic pouches
Appearance	Clear
Formula	Not applicable (Mixture)
Molecular mass	Not applicable (Mixture)
Color	Colorless
Odor	No data available
Odor threshold	No data available
pH	3.5 – 6.0
Melting point	Not applicable
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Relative evaporation rate (butyl acetate=1)	No data available
Flammability (solid, gas)	No data available
Vapor pressure	No data available
Relative vapor density at 20°C	No data available
Relative density	3 mM Solution – 1.005 6 mM Solution – 1.007
Solubility	Miscible in water; Organic solvents : Miscible with Alcohols, Acetone, THF, DMF, DMSO
Log Pow	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosion limits	No data available
Explosive properties	No data available
Oxidizing properties	No data available

SECTION 10: Stability and reactivity

Reactivity	The product is non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at room temperature when stored according to label instructions.
Possibility of hazardous reactions	No dangerous reactions known under normal conditions of use.
Conditions to avoid	None under recommended storage and handling conditions (see section 7).
Incompatible materials	UV light exposure and strong oxidants, e.g. peroxides, permanganates, perchlorates, nitric acids.
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Likely routes of exposure None likely for packaged product. Bulk material may be absorbed by inhalation, skin contact and ingestion.

Toxicological information

Acute toxicity

Component	Type	Dose
Amotosalen HCl	LD50 Oral rat	885 mg/kg
	LD50 IV rat	250 mg/kg

Additional information	No data available
Serious eye damage/irritation	Amotosalen was irritating to the eyes of rabbits; Aqueous 1 mg/mL formulations were non-irritating.
Skin corrosion/irritation	Amotosalen was irritating to the skin of rabbits; Aqueous 1 mg/mL formulations were non-irritating.
Sensitization	Amotosalen was a weak contact sensitizer in guinea pigs at 25 mg/mL but not 1 mg/mL. It was a positive photosensitizer in guinea pigs and rats.
STOT-single exposure	Following single dose intravenous (IV) administration of amotosalen in dogs and rats, the NOELs were 30 and 236 mg/kg, respectively.
STOT-repeated exposure	No evidence of toxicity was observed in rats and dogs treated with intravenous (IV) doses of amotosalen for 7-28 days at doses ≥30,000 or ≥10,000 fold above the expected human dose, respectively. An IV dose of amotosalen in male rats followed by UVA activation resulted in increased incidence of skin and eye effects at 10 mg/kg/ hour, but not at 1 mg/kg/hour, for one hour.
Reproductive toxicity	No adverse effects on fertility were noted in male or female rats administered amotosalen (further details not identified).
Developmental toxicity	No adverse effects were identified in studies evaluating amotosalen in pregnant rats and rabbits (further details not identified).
Genotoxicity	Amotosalen was negative in a number of *in vivo* and *in vitro* genotoxicity assays. Amotosalen was positive in a Chinese hamster ovary test for chromosome aberrations in the presence of metabolic activation, in a mouse lymphoma gene mutation assay, and in a single strain in an Ames test. Overall, amotosalen is unlikely to be genotoxic.
Carcinogenicity	No carcinogenicity was observed in transgenic mice treated three times weekly with intravenous amotosalen for 6 months at cumulative weekly doses ~1200 times the daily human exposure from a single transfusion. None of the components of this product/mixture is listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data available
Experience with humans	See "Section 2 - Other Hazards".

SECTION 12: Ecological information

Toxicity

Component	Type	Concentration
Amotosalen HCl	No data available	No data available

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

SECTION 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.

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 class(es) (DOT)	None assigned.
Packing group	None assigned.
Marine pollutant	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special transport precautions	Avoid release to the environment.
Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	No chemical safety assessment has been carried out.
TSCA	Drugs are exempt from TSCA.
SARA Section 313 - Emission Reporting	This substance or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.
California Proposition 65	California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.
Additional information	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

SECTION 16: Other information

Full text of H phrases and GHS classification	Acute Tox. 4 (Oral) - Acute toxicity (oral) Category 4. Eye Irrit. 2 - Serious eye damage/eye irritation Category 2. Skin Irrit. 2 - Skin corrosion/irritation Category 2. Skin Sens. 1B - Skin sensitization, category 1B. H302 - Harmful if swallowed. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation.
Data sources	Information from published literature and internal company data.
Abbreviations and acronyms	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; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
Issue date	17 September 2023
Current revision	4.0
Indication of changes	This is the fourth 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 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 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.