	SPECIFICATION	SPC 00314	2.0
CERUS	SAFETY DATA SHEET Amotosalen Hydrochloride Solution		

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

For USA and Rest of World
Cerus Corporation
2550 Stanwell Drive
Concord, CA 94520
E-mail: EHS@cerus.com
Main:1-925-288-6000

For Europe:
Cerus Corporation B.V.
Stationsstraat 79-D
3811 MH Amersfoort
The Netherlands

Emergency telephone number: Chemtrec

+1 (800) 424-9300 (USA and Canada)
+1 (703) 527-3887 (Collect calls accepted)

Product identifier	Amotosalen Hydrochloride Solution
Synonyms	S-59, 3-[(2-aminoethoxy)methyl]-2,5,9-trimethyl-7H-furo[3,2-g][1]benzopyran-7-one hydrochloride
Trade names	Not applicable
Chemical family	Aqueous solution containing a psoralen.
Relevant identified uses of the substance or mixture and uses advised against	Isotonic solution containing active pharmaceutical ingredient which is used in combination with ultraviolet light (UVA) target nucleic acid and prevents replication of DNA and RNA. The intended use is as a component of the INTERCEPT™ Blood System for pathogen inactivation.
Note	The pharmacological, toxicological and ecological properties of this mixture and/ or its ingredients have not been fully characterized. This SDS will be revisited as more data become available.
Date Prepared	8 April 2013

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS]	Skin Sensitizer - Category 1. Mixture not yet fully tested.
Directive 67/548/EEC or 1999/45/EC	Xi - R43. Mixture not yet fully tested.

SECTION 2: HAZARDS IDENTIFICATION (CONT.)

Label elements

CLP/GHS hazard pictogram

CLP/GHS signal word Warning.

CLP/GHS hazard statements H317 - May cause allergic skin reaction.

CLP/GHS precautionary statements P261 - Avoid breathing dust. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear eye/face protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger

Xi - Irritant

Risk (R) Phrase(s) R43 - May cause sensitization by skin contact.

Safety Advice S2 - Keep out of reach of children. S24 - Avoid contact with skin. S36/37 - Wear suitable protective clothing and gloves. S46 - If swallowed, seek medical advice immediately and show this container or label.

Other hazards Sensitization reactions may occasionally occur, but are not common.

US Signal word Warning

US Hazard overview May cause allergic skin reaction. Mixture not yet fully tested.

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. See Section 16 for full text of EU and GHS classifications. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. The CLP/GHS classifications are based on Regulation (EC) 1272/2008. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	EU Classification	GHS Classification
Amotosalen Hydrochloride	161262-45-9	N/A	0.1-0.2%	Harmful: Xn - R22; R36/38; R43	ATO4: H302; SI2: H315; EI2: H319; SS1: H317

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 EU-CLP/GHS classifications. The EU classification is based on Directive 1999/45/EC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 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 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. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug-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 and carbon dioxide, oxides of nitrogen, and chlorine-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
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.

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 mist/spray.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	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. Wash spill area thoroughly with water. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13).
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling	Follow recommendations for handling potent compounds (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact. Wash thoroughly after handling.
Conditions for safe storage including any incompatibilities	Store in a closed container protected from light at room temperature (25ºC) or lower.
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/syringes in a sharps container.

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Amotosalen Hydrochloride	Cerus Corporation	OEL-TWA 8-Hr	70 µg/m³

Exposure/Engineering controls

Control exposures to below the OEL. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. This chemical should be handled as a Potent compound (Category 3 of 4). 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 aerosol.

Respiratory protection

None required if the material is handled in a sealed container (e.g., as part of the INTERCEPT Processing Set). If handling bulk solution: 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 provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate 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 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.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (CONT.)

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid.
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	3.5-7.0
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.
Solvent solubility	No information identified.
Partition coefficient (*n-octanol/water*)	No information identified.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (CONT.)

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	337.8 (Amotosalen Hydrochloride)
Molecular formula	$C_{17}H_{19}NO_4HCl$ (Amotosalen Hydrochloride)

SECTION 10: STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable at room temperature when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	No information identified.
Incompatible materials	UV light exposure and strong oxidants, e.g., peroxides, permanganates, perchlorates, nitric acids
Hazardous decomposition products	No information identified.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

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

Acute toxicity

Compound	Type	Route	Species	Dose
Amotosalen Hydrochloride	LD_{50}	Oral	Rat	885 mg/kg
	Minimum lethal dose	Oral	Rat	500-742 mg/kg
	Single tolerated dose	Oral	Rat	236 mg/kg
	Minimum lethal IV dose	Intravenous	Rat	210-250 mg/kg
	Single tolerated dose	Dermal	Rabbit	2 g/kg

Additional acute toxicity information Rats were given S-59 by intravenous infusion for one hour at doses of 0.01, 0.1, 1.0, and 10.0 mg/kg, and a dorsal skin site and both eyes were then exposed to UV radiation within 15 minutes of dosing. Dermal changes indicative of phototoxicity (erythema, edema, and/or flaking) were present in male rats given 10 mg/kg of S- 59 and in female rats given 1 or 10 mg/kg. Ophthalmologic changes indicative of phototoxicity (keratits, miosis, and/or chemosis) were present in rats given 10 mg/ kg of S-59. Additionally, control and lower-dosage female rats had dermal changes including erythema that indicated a greater than expected sensitivity to UV radiation alone.

Irritation/Corrosion S-59 when applied topically by the ocular route (as a solid powder) and by the dermal route (in a 25 mg/mL aqueous formulation) showed evidence of irritation in rabbits. Aqueous 1 mg/mL formulations were non-irritating. Evidence of dermal photoirritation was present in rabbits when S-59 treated skin sites were exposed to 10 J/cm^2 UVA light. In the unprotected rabbit eye, opthalmoscopic changes were present in the conjunctiva, iris, cornea, and aqueous humor at dermal doses of > 240 mg S-59. The related compound 8-methoxypsoralen is known to cause photo-ocular lesions in rabbits.

Sensitization Guinea pig dermal sensitization studies showed a weak delayed contact sensitization potential with a 25 mg/mL formulation of S-59, while S-59 powder material and a 1 mg/mL formulation were negative in this assay. In guinea pig dermal photosensitization studies, S-59 powder showed contact photosensitization potential and a 1 mg/mL formulation showed slight contact photosensitization potential.

SECTION 11: TOXICOLOGICAL INFORMATION (CONT.)

STOT-single exposure	No data available.
STOT-repeated exposure/Repeat-dose toxicity	Repeated dose studies in laboratory animals have shown that S-59 does not cause significant systemic toxicity at fairly high doses when given intravenously (greater than 1 gram/day equivalent human exposure). Based on animal studies, if S-59 is repeatedly absorbed, effects on the skin and eyes could occur if the exposed individual is concomitantly exposed to sunlight. These effects could include sunburn-like reactions to the skin, and/or injury to the eye.
Reproductive toxicity	No studies identified.
Developmental toxicity	No studies identified.
Genotoxicity	S-59 was positive for genotoxic effects in the following assays: an Ames bacterial cell mutagenicity assay, a mouse lymphoma gene mutation assay, and a chromosomal aberration assay. It was not mutagenic in an *in vivo* assay that evaluated effects on the DNA of rats, nor in a mouse micronucleus assay, which evaluated chromosomal effects.
Carcinogenicity	Intravenous administration of photochemically treated 35% plasma or unilluminated 150 µM active ingredient (1 mg/kg) in 35% plasma given 3 times/week for 26 weeks was not carcinogenic in transgenic mice heterozygous for the p53 tumor-suppressor gene. The p53 carcinogenicity assay is a sensitive model for genotoxic carcinogens. This substance 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"

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Amotosalen Hydrochloride	--	--	--

Persistence and Degradability	No data identified.
Bioaccumulative potential	No data identified.
Mobility in soil	No data identified.
Results of PBT and vPvB assessment	Not performed.

SECTION 12: ECOLOGICAL INFORMATION (CONT.)

Other adverse effects	No data identified.
Note	The environmental characteristics of this substance 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 substance 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 substance 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.

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 or regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Yes. Warning. May cause allergic skin reaction. Substance 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.
WHMIS symbol(s)	 Class D – 2B
TSCA status	Not listed.
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16: OTHER INFORMATION

Full text of R phrases and EU Classifications	Xn - Harmful. R22 - Harmful if swallowed. R36/38 - Irritating to eyes and skin. R43 - May cause sensitization by skin contact.
Full text of H phrases, P phrases and GHS classification	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. SI2 - Skin irritant Category 2. H315 - Causes skin irritation. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation.
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, Labeling, 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;

SECTION 16: OTHER INFORMATION (CONT.)

Abbreviations (cont.)

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

Updated contact information in Section 1. Reviewed and revised according to current regulations and directives, including updated formatting in accordance with General US, EU, and GHS (EU CLP) requirements.

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.