

NEOLONE™ M-10

Preservative for Household and I&I Products

Broad Spectrum Bactericide for Global Formulations

Rohm and Haas Company, the world's leading supplier of antimicrobial technology, introduced KATHON™ CG/ICP preservative for household and industrial and institutional (I&I) applications in the early 1980's. Now, our unique knowledge of isothiazolinone chemistry has resulted in NEOLONE biocides. These broad spectrum biocides are particularly suitable as replacements for formaldehyde donors in:

- liquid laundry products
- all purpose liquid cleaners
- furniture and floor care products
- high pH surfactant systems
- other aqueous raw materials

NEOLONE M-10 is specifically formulated for household and I&I applications. This new preservative provides formulators of household and I&I products with a formaldehyde-free biocidal solution. NEOLONE M-10 preservative is effective at very low use levels and is stable in difficult to preserve high pH formulations. And NEOLONE M-10 is supported by extensive toxicology studies and global regulatory dossiers.

Benefits of NEOLONE M-10

- Broad spectrum biocide
- Effective alternative to formaldehyde donors
- Easy to dose and highly water soluble
- Effective at low use levels
- Excellent stability in a variety of matrices over a wide range of pH (2 to 12) and temperatures
- Compatible with a variety of fungicides and bactericides
- Compatible with a wide range of household and I&I raw materials including surfactants and emulsifiers
- Safe to use at recommended use levels
- Excellent environmental profile: rapidly degrades, does not bioaccumulate and is non-persistent in the environment

We Supply More Than a Preservative

In the current regulatory climate where more and more data are required by regulatory authorities, it is important not only to choose a high purity and consistent quality preservative, but also the right supplier who is able to give you the technical, regulatory and commercial support that you need. Rohm and Haas has more than 30 years of experience with isothiazolinone chemistry and over 100 patents. To support the use of our products, we maintain the following information on NEOLONE M-10:

- Complete regulatory dossiers
- Extensive toxicological databases
- Environmental fate database that is continually updated
- Safe handling expertise that can help you in your manufacturing facilities
- Technical expertise with isothiazolinone chemistry
- Public relations/media expertise

Physical and Chemical Properties

Chemical Identification

The active ingredient of NEOLONE preservative is an isothiazolinone identified by the Chemical Abstract and IUPAC system of nomenclatures as 2-Methyl-4-isothiazolin-3-one and 2-Methyl-3(2H)isothiazolinone.

EPA Reg. No.	CAS Number	Empirical Formula
707-256	2682-20-4	C ₄ H ₅ NOS

Typical Properties

NEOLONE M-10 preservative provides 9.5% active ingredient in water. Every batch of NEOLONE M-10 is manufactured to exact specifications, and a certificate of analysis can be provided with each order.

Typical Properties

These properties are typical but do not constitute specifications.

A.I. Content	9.5% in water
Appearance	Clear liquid
Color	APHA < 100
pH	3 to 6
Specific gravity	1.02
Solubility	totally miscible in water, lower alcohols and glycols, low solubility in hydrocarbons
Stability	one year at ambient temperatures and at least six months at 50°C

Current Regulatory Status

NEOLONE M-10 for Global Formulations

Extensive databases and global expertise provide Rohm and Haas with a solid foundation for obtaining registration and global approval for NEOLONE M-10.

Please check our website www.rohmhaas.com for the current regulatory status of NEOLONE M-10.

Recommended Use Directions

The recommended use level for NEOLONE M-10 is 0.053%-0.158% (50-150 ppm of active ingredient) of NEOLONE M-10 as supplied.

NEOLONE M-10 preservative should be added as the last ingredient and at the lowest temperature (<45°C) if possible. Since the components of household and I&I formulations vary considerably and may impact on the effect of preservatives, we urge each manufacturer to confirm the efficacy and stability of NEOLONE M-10 in use.

PPM	Active ingredient	% Product
	%	NEOLONE M-10
50	0.0050	0.053
75	0.0075	0.079
100	0.0100	0.105
150	0.0150	0.158

Application Versatility

NEOLONE M-10 preservative can be effectively used in any of the following applications:

- liquid laundry products
- all purpose liquid cleaners
- furniture and floor care products
- high pH surfactant systems
- other aqueous raw materials

Microbiological Efficacy

NEOLONE M-10 preservative exhibits outstanding antimicrobial activity, inhibiting a wide variety of gram positive and gram negative bacteria, yeast and molds. The following table gives the minimum inhibitory concentration (MIC) in ppm active ingredient methylisothiazolinone, which inhibited the growth of various microorganisms in broth tests.

Organism	ATCC No.	MIC (ppm a.i.)
Bacteria		
<i>Enterobacter aerogenes</i>	15038	30
<i>Pseudomonas aeruginosa</i>	15442	40
<i>Burkholderia cepacia</i>	17765	20
<i>Pseudomonas oleovorans</i>	8062	30
<i>Pseudomonas putida</i>	795	20
<i>Staphylococcus aureus</i>	6538	40
<i>Serratia marcescens</i>	Lab Isolate	30
<i>Test Parameters: Nutrient Broth, 30°C/pH 7, 24 Hour Contact Time.</i>		

Conclusion

NEOLONE M-10 preservative inhibits a wide variety of bacteria at low active ingredient levels.

Proven Performance in Household and I&I Applications

The microbiological performance of NEOLONE M-10 preservative in most products is excellent.

Long-term microbiological protection is obtained employing use levels up to 150 ppm of active ingredient. Typical use levels for most household and I&I products are in the range of 50 ppm to 150 ppm of active ingredient. For each formulation, it is important to ensure stability of the active ingredient and assess the efficacy through a microbiological challenge test. The following tables illustrate the results obtained when evaluating the preservative efficacy of NEOLONE M-10 in a variety of household and I&I products.

Rohm and Haas typically uses a 4-week challenge test with separate inoculation of a mixed pool of common spoilage bacteria and a mixed pool of common spoilage fungi, coupled with an analysis of the active ingredient by High-Performance Liquid Chromatography (HPLC).

The bacterial and fungal efficacy of NEOLONE M-10 preservative was determined in sodium lauryl ether sulfate and a liquid laundry detergent by dosing samples with the manufacturer's recommended use level of preservative. One set of samples was inoculated at time zero with a mixed pool of bacteria to obtain 10^7 CFU/g of sample; a duplicate set was inoculated with a mixed pool of fungi to obtain 10^7 CFU/g of sample. Bacterial samples were stored at 30°C and fungal samples were stored at 25°C for the duration of the test. The samples were monitored for viable microorganisms at 7, 14 and 28 days after inoculation using standard plating methods. The preservative was deemed effective if no microorganisms survived in the samples.

Efficacy of NEOLONE M-10 in Sodium Lauryl Ether Sulfate

Preservative	Concentration (% a.i.)	CFU/g ¹ after day:		
		7	14	28
Bacteria				
Unpreserved control	0	2.6×10^7	4.0×10^7	4.4×10^6
NEOLONE M-10	0.0050	<10	<10	<10
Fungi				
Unpreserved control	0	4.0×10^7	1.8×10^7	2.6×10^7
NEOLONE M-10	0.0050	<10	<10	<10

¹limit of detection of the test is 10 CFU/g; <10 indicates that there were no colonies on the plate.

Efficacy of NEOLONE M-10 in a Liquid Laundry Detergent

Preservative	Concentration (% a.i.)	CFU/g ¹ after day:		
		7	14	28
Bacteria				
Unpreserved control	0	$>10^5$	$>10^5$	$>10^5$
NEOLONE M-10	0.0050	<10	<10	<10
Fungi				
Unpreserved control	0	$>10^5$	$>10^5$	$>10^5$
NEOLONE M-10	0.0075	<10	<10	<10

¹limit of detection of the test is 10 CFU/g; <10 indicates that there were no colonies on the plate.

Efficacy of NEOLONE M-10 in a Floor Polish

Preservative	Concentration (% a.i.)	CFU/g ¹ after day:	
		7 ²	14
Bacteria			
Unpreserved control	0	9.7 x 10 ⁴	1.8 x 10 ⁶
NEOLONE M-10	0.0050	<10	<10

¹ limit of detection of the test is 10 CFU/g; <10 indicates that there were no colonies on the plate.

² samples were re-inoculated with 6.6 x 10⁷ CFU/g of mixed bacterial pool at one week

Efficacy of NEOLONE M-10 in an All-Purpose Liquid Cleaner

Preservative	Concentration (% a.i.)	CFU/g ¹ after day:		
		7	14	28
Bacteria				
Unpreserved control	0	2.3 x 10 ⁸	1.9 x 10 ⁸	4.6 x 10 ⁷
NEOLONE M-10	0.0050	<10	<10	<10

¹ limit of detection of the test is 10 CFU/g; <10 indicates that there were no colonies on the plate.

The bacterial efficacy of NEOLONE M-10 preservative was determined in a floor polish and an all-purpose liquid cleaner by dosing samples with the manufacturer's recommended use level of preservative. The samples were inoculated at time zero with a mixed pool of bacteria to obtain 10⁵ - 10⁷ CFU/g of sample. Samples were stored at 30°C for the duration of the test. Floor polish samples were monitored for viable microorganisms at 7 and 14 days after inoculation using a standard pour plate method. These samples were reinoculated after the one week plating. The all-purpose liquid cleaner samples were monitored for viable microorganisms at 7, 14 and 28 days after inoculation using a standard pour plate method. The preservative was deemed effective if no microorganisms survived in the samples.

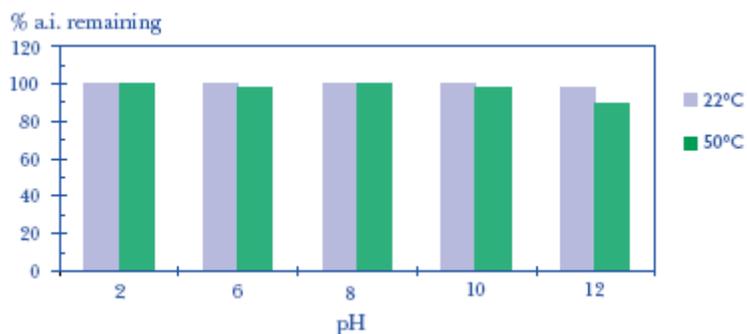
Conclusion

NEOLONE M-10 is effective at 50 to 150 ppm active ingredient in household and I&I products.

Chemical Stability

NEOLONE M-10 preservative shows excellent stability in household and I&I formulations and with aqueous raw materials. NEOLONE M-10 preservative is stable over a wide range of pH and temperature conditions and is compatible with a variety of surfactants. The active ingredient is stable in surfactants, laundry products, floor care products, and all-purpose cleaners. The data below demonstrates these formulation advantages.

Effect of pH and Temperature in Buffered Water (Methylisothiazolinone Stability After 3 Weeks)



NEOLONE M-10 Stability in Surfactants

Matrix	% Active ingredient remaining at 4 weeks:		
	25°C	42°C	50°C
Sodium lauryl ether sulfate	100	100	100
Sodium lauryl sulfate	100	100	100
Cocamidopropyl betaine	100	85	66
Sodium C ₁₄₋₁₆ olefin sulfonate	100	93	79
Ammonium lauryl sulfate	100	98	100
Sodium dodecylbenzene sulfonate	100	100	not done
Sodium lauroyl sarcosinate	84 (52 weeks at 25°C)		

NEOLONE M-10 Stability in Household and I&I products

Conclusions

NEOLONE M-10 preservative is stable over a wide range of pH and temperature conditions.

NEOLONE M-10 preservative is stable in a variety of raw materials and household and I&I products, including surfactants, laundry products, floor care products, and all-purpose cleaners.

Matrix	Temperature °C	Time Weeks	% Active ingredient Remaining
Laundry Products			
<i>Fabric wash concentrate</i>	45	4	96
<i>Laundry detergent</i>	40	4	100
Floor Care Products			
<i>Floor finish</i>	45	4	90
<i>Floor polish</i>	40	12	100
Liquid Cleaners			
<i>Waterless hand cleaner</i>	40	12	99
<i>Shower cleaner</i>	40	12	100
<i>Dish detergent</i>	40	12	100
<i>Scrub product</i>	40	12	100

Analytical Procedures

High Performance Liquid Chromatography (HPLC)

HPLC analysis is the preferred method for determining low levels of NEOLONE M-10. This method can be used to determine NEOLONE M-10 levels in many household and I&I products. If you require detailed information on HPLC methods, please contact your local Rohm and Haas sales office for the current bulletin.

Consumer Safety

The toxicology of the active ingredient of NEOLONE M-10 preservative, methylisothiazolinone, has been assessed in an extensive battery of non-clinical and clinical testing. Results of these studies have demonstrated that NEOLONE M-10 does not present a mutagenic, teratogenic, reproductive or carcinogenic risk to humans.

The use of NEOLONE M-10 at recommended use levels is safe. This is supported by our extensive toxicological and clinical databases, our work with dermatologists worldwide and more than 20 years experience with safe use of isothiazolinone chemistry in a large number of household and I&I products worldwide. For further details on the complete toxicological profile of NEOLONE M-10, please contact your local Rohm and Haas Account manager.

Acute Toxicity of NEOLONE M-10:

Test method	Findings
Acute oral toxicity, rat	LD ₅₀ = 2834 mg/kg (m), 1091 mg/kg (f)
Acute dermal toxicity, rat	LD ₅₀ >5000 mg/kg (m&f combined)
Skin irritation, rabbit	Non-irritating when tested at maximum use concentration of 100 ppm a.i.
Eye irritation, rabbit	Non-irritating when tested at maximum use concentration of 100 ppm a.i.
21-day cumulative irritation and sensitization study, human	Threshold for irritation and sensitization is at or above 1000 ppm a.i.
Skin sensitization, human repeat insult patch tests (HRIPT)	No evidence of sensitization in subjects when tested up to and including 300 ppm a.i.
Phototoxicity test, human	No evidence of phototoxicity when tested at 200 ppm a.i.
Photoallergy test, human	No evidence of photoallergy when tested at 200 ppm a.i.

Note: a.i. = active ingredient

Mutagenicity Tests with Methylisothiazolinone

Test method	Findings
Ames bacterial mutation assay, 4 strains of <i>Salmonella typhimurium</i>	Negative (not mutagenic)
Gene mutation at the HGPRT locus in cultured Chinese hamster ovary cells	Negative (not mutagenic)
<i>In Vitro</i> cytogenetic assay (chromosome aberrations in Chinese hamster ovary cells)	Negative (not mutagenic)*
<i>In Vivo</i> cytogenetic assay (micronucleus assay in mice)	Negative (not mutagenic)

* An increase in chromosomal aberrations was observed, but only in presence of marked cytotoxicity.

Responsible Manufacturing

A preservative is formulated into household and I&I products principally to protect them from chance microbial contamination during production, storage and final customer use. It should not be expected to cope with severe contamination problems brought about by poor manufacturing practices. In the manufacturing plant, it is important that all potential sources of microbial contamination are identified and controlled. Some of the important sources of microbial contamination include:

- raw materials
- water supplies
- poor housekeeping and plant design
- poor hygiene
- inadequate cleaning and sanitization protocols
- product reworking

Once identified, steps can be taken to control the level of contamination. Good manufacturing practices, backed-up by regular and effective monitoring programs, are key factors. See Rohm and Haas publication "Preventing Microbial Contamination In Manufacturing." You can request a copy on our web site at www.rohmhaas.com.

Environmental Information

Rohm and Haas is continually expanding its already extensive knowledge on the environmental fate and toxicity of isothiazolinone preservatives. NEOLONE M-10 preservative has the following environmental properties:

- Low use levels
- Rapidly biodegrades to non-toxic substances
- Not persistent in the environment
- Halogen free

- Does not affect the performance of wastewater treatment plants
- Does not bioaccumulate
- Predicted environmental concentration (PEC) will be significantly less than the toxic threshold and thus will have minimal environmental impact

A summary of the current environmental chemistry and toxicology data for NEOLONE M-10 preservative follows.

Environmental Fate

Parameter	Value
Water solubility	>50%
Log P (octanol/water)	- 0.5
Bioconcentration factor (BCF)	3
Biodegradation	Inherently biodegradable (56% mineralization to CO ₂)
Hydrolytic half-life	>30 days (stable)
Photolytic half-life	11 days
Half-life in biological microcosm (metabolites are about 5 orders of magnitude less toxic than parent)	9 hours

Ecotoxicology

Organism	Acute toxicity value*
Rainbow trout	6 ppm (96 hr LC ₅₀)
Bluegill sunfish	10 ppm (96 hr LC ₅₀)
Daphnia magna	1.9 ppm (48 hr EC ₅₀)
Green algae	0.1 ppm (72 hr EC ₅₀)
Activated sludge Respiration inhibition	41 ppm (3 hr EC ₅₀)

* Results expressed in active ingredient

These results demonstrate that NEOLONE M-10 preservative does not bioaccumulate in organisms (Log P <3 and BCF significantly below 100) and biodegrades very rapidly in the environment to metabolites that have minimal toxicity. An environmental risk assessment based on this information coupled with the extensive environmental data base for KATHON® CG preservative demonstrates that recommended use levels of NEOLONE M-10 preservative in household and I&I products will have minimal environmental impact.

Safe Handling

Personal Protective Equipment

You can count on Rohm and Haas personnel to provide you with advice and assistance on the safe handling of NEOLONE M-10 preservative in your plant. The following handling precautions should be observed with the product as supplied:

Material is CORROSIVE. Do not get in eyes, on skin, or on clothing.

Causes eye damage and skin burns. May cause allergic skin reaction. May be harmful if swallowed or absorbed through the skin. Keep away from children.

Wear appropriate safety gear when handling.

Wear goggles or safety glasses, face shield and gloves (butyl rubber or nitrile) when handling. Avoid breathing vapor or mist. Avoid contamination of food. Do not take internally. Wash thoroughly after handling.

First Aid Measures

After contact with eyes: FLUSH IMMEDIATELY with copious amounts of water for at least 15 minutes, with the eyes held open. Get prompt medical attention but FLUSH FIRST.

After contact with skin: FLUSH IMMEDIATELY with plenty of water for at least 15 minutes. Remove and launder contaminated clothing. Wash affected skin thoroughly with soap and water. Wash thoroughly even if no skin burns are present since they may become apparent only after long contact time following inadequate washing.

If inhaled: Remove casualty immediately to fresh air. If not breathing, apply artificial respiration. If breathing is difficult, give oxygen. Call a physician immediately.

If ingested: Dilute the ingested product by giving water to drink. Call a physician at once. Never give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Corrosive material. Probable mucosal damage may contraindicate the use of gastric lavage. It is inadvisable to induce vomiting. Measures against circulatory shock, respiratory depression, and convulsions may be needed.

Disposal of Spilled and Waste Material

NEOLONE M-10 preservative as supplied, is toxic to fish and wild-life. Spills and cleaning run-offs should not be discharged where they can drain into sewage treatment plants, lakes, streams, ponds, or other public water. Follow the disposal methods given on the package label and observe all federal, state, and local regulations.

NEOLONE M-10 preservative containing wastes must not be discharged into public waters or sewage treatment systems. Such wastes must be deactivated (see below) and adequately diluted before discharge into any public water or sewage treatment facility. When considering disposal of any waste, observe all federal, state, and local regulations.

Deactivation – General

Absorb spills with spill pillows or inert solids (vermiculite) and transfer contaminated materials to containers for disposal.

Deactivate spill area or equipment with a freshly prepared solution of 5% sodium hypochlorite (household bleach as is) and 3 to 5% solid sodium bicarbonate. DO NOT add deactivation solution to the waste pail to deactivate the adsorbed material.

Apply 10 times of deactivating solution per estimated volume of residual NEOLONE M-10 to deactivate any remaining active ingredient. Let stand for 30 minutes.

Rinse the spill or equipment with copious amounts of water and drain to chemical sewer (if in accordance with federal, state, and local regulations).

Personnel making up or handling deactivation solutions should wear goggles or face shield, rubber apron and full length butyl rubber or nitrile gloves.

Deactivation - Preparation of Equipment for Maintenance

Mixing vessels, lines and pumps and other equipment containing residues of NEOLONE M-10 preservative must be deactivated before carrying out maintenance or repair work or using for other service. Drips, spills and exposed wet areas and valves should be cleaned up promptly with deactivation solution.

To deactivate the surfaces of equipment, swab with deactivation solution, wait 30 minutes and rinse thoroughly with clean water. Soak tools, pails, funnels and lines with deactivation solution for 30 minutes and then rinse with water.

To determine the amount of deactivation solution needed for clean up, estimate the volume of NEOLONE M-10 preservative solution remaining in a well drained system of vessels, lines and pumps, and make-up and charge 10 volumes of deactivation solution per volume of preservative solution, wait for 30 minutes and then add more water to provide thorough mixing and contact throughout the equipment. Circulate the mixture through the system for about 30 minutes, then drain and rinse with clean water or detergent solution. Drain to a municipal or chemical sewer if in accordance with federal, state, and local regulations.

Deactivation - Clothing

Contaminated clothing must be deactivated prior to laundering. Soak the clothing with deactivation solution for 30 minutes and then rinse with water. To determine the amount of deactivation solution needed for clean up, estimate the volume of NEOLONE M-10 preservative that may have been spilled on the clothing and make-up and charge 10 volumes of deactivation solution per volume of preservative solution, wait for 30 minutes and then add more water to provide thorough mixing and contact throughout the clothing. Soak for about 30 minutes, then drain and rinse with clean water or detergent solution. Drain to a municipal or chemical sewer if in accordance with federal, state, and local regulations. The deactivated clothing should then be laundered, preferably by a commercial laundry before being worn.

Contaminated leather articles, such as work boots and gloves, should be deactivated and then disposed. Under no circumstances should leather articles be worn after contamination.

Deactivation - Cleanup of Spills

Personnel cleaning up spills should wear appropriate protective clothing. This should include a rubber apron or impervious jacket, impervious full length butyl rubber or nitrile gloves, footwear, chemical splash goggles and optionally a half face piece respirator with organic vapor/acid gas cartridge and dust/mist prefilter. Spilled material should be diked and absorbed on a spill control pillow or onto an inert solid such as clay or vermiculite. Shovel the absorbent and the soil beneath it to a depth sufficient to remove all preservative into a pail or drum. This material should then be disposed of in accordance with federal, state and local regulations; our recommended method of disposal is incineration. Any residual NEOLONE M-10 preservative remaining on the spill site should then be treated with deactivation solution. A weight ratio of ten parts deactivation solution to one part NEOLONE M-10 should be used for this treatment. After allowing 30 minutes contact time, rinse the area with copious amounts of water and flush to the sewer if in accordance with federal, state, and local regulations. Note: Do not add deactivation solution to the waste pail.

Material Safety Data Sheets

Material Safety Data Sheets (MSDS) are available for all Rohm and Haas products. These sheets contain pertinent information that you may need to protect your employees and customers against any known health or safety hazards associated with our products. We recommend that you obtain copies of our MSDS from your local Rohm and Haas technical representative before using our products in your facilities. We also suggest that you contact your suppliers of other materials recommended for use with our products for appropriate health and safety precautions before using them.

NEOLONE is a trademark of Rohm and Haas Company, or of its subsidiaries or affiliates. The Company's policy is to register its trademarks, where products designated thereby are marketed by the company, its subsidiaries or affiliates.

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Suggestions for uses of our products or the inclusion of descriptive material from patents and the citation of specific patents in this publication should not be understood as recommending the use of our products in violation of any patent or as permission or license to use any patent of the Rohm and Haas Company.

Material Safety Data Sheets outlining known health and safety hazards and handling methods for our products are available on request.

