DOWICIL 200 Preservative

Reliable, broad-spectrum antimicrobial protection
for cosmetics and personal care formulations

DOWICIL 200 Preservative offers an ideal combination of properties for preserving most cosmetic and personal care products

More and more, formulation chemists, microbiologists and toxicologists are specifying DOWICIL* 200 Preservative for antimicrobial protection in cosmetic and personal care formulations. There is no single reason why. Rather, it's because DOWICIL 200 offers a unique combination of desirable properties. Here's an initial look at some of those properties, and how they may prove beneficial in your new or existing formulation.

Effective at low concentrations

DOWICIL 200 Preservative is highly effective at low concentrations. Typically, 0.02 to 0.2% by weight of DOWICIL 200 provides dependable antimicrobial activity in most formulations.

Broad spectrum effectiveness

When you formulate with DOWICIL 200, you're working with a material that's proven effective against a broad variety of bacteria, yeasts and molds.

Excellent formulation compatibility

The many formulations that include DOWICIL 200 are the best testament to its compatibility with an enormous variety of ingredients and total formulation systems. The antimicrobial activity of DOWICIL 200 is independent of system pH between 4 and 10, and it displays excellent compatibility with proteinaceous matter. Moreover, DOWICIL 200 is not inactivated by nonionic, anionic or cationic formulation ingredients.

Well-documented, favorable toxicologic profile

Extensive toxicologic studies conducted on DOWICIL 200 Preservative both at Dow laboratories and in independent institutions show a quite favorable toxicologic profile for this product. Well-documented skin, eye and ingestion studies have been conducted in animals, and additional irritation and sensitization studies have been conducted in humans. The results indicate that DOWICIL 200 should not present any hazards through its proper handling during manufacturing or use by the consumer in finished products. Further information is available through your Dow representative.

High water solubility, virtually insoluble in oil

DOWICIL 200 is highly soluble in water, while remaining virtually insoluble in oils or organic solvents. As a result, it stays in the aqueous component of your formulation, where microorganisms can live. That can mean less preservative is needed to protect the total formulation and that means lower costs.

Shelf life in formulations

At the dilute levels (typically 0.02 to 0.2%) used in finished formulations, DOWICIL 200 Preservative remains highly effective for two or more years.

Cost effective

When you formulate with DOWICIL 200, you're working with one of the most cost-effective preservatives available. Because it's highly effective at low concentrations, DOWICIL 200 shouldn't represent more than a small fraction of your total formulation costs.

Easy to work with

DOWICIL 200 is remarkably easy to incorporate into your formulation. You get the flexibility to work with a highly uniform, free-flowing powder that disperses and dissolves readily into the water phase of your formulation. You can also premix DOWICIL 200 into an aqueous concentrate just before adding it to your formulation. Either way, you get the same reliable antimicrobial effectiveness.

The following pages will give you a closer look at some of the properties of DOWICIL 200 Preservative discussed here only briefly.

You'll discover some of the reasons for its broad compatibility, and learn about Dow services that can provide considerable assistance as you develop your formulation. There's also more detailed technical information about DOWICIL 200, including toxicologic properties, formulating considerations, and proper handling methods.

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DOWICIL 200 Preservative is compatible with a broad array of cosmetic and personal care formulations

Given the almost unlimited number of potential combinations of ingredients for cosmetic and personal care products, it's impossible to guarantee that any one preservative will be compatible with all formulations.

On the other hand, the sheer weight of variety and numbers of formulations currently using DOWICIL 200 makes a convincing case for its broad compatibility with ingredient materials and formulation systems.

Now in thousands of formulations

DOWICIL 200 Preservative is currently providing safe, effective antimicrobial performance in thousands of formulations. And those formulations are a cross-section of almost all types of cosmetic and personal care products.

There are a number of identifiable reasons for the popularity of DOWICIL 200.

Low concentration

One reason is that DOWICIL 200 is effective at low concentrations – typically 0.02 to 0.2% by weight in formulations.

Active from pH 4 through 10

The antimicrobial activity of DOWICIL 200 is essentially uniform between pH 4 and pH 10. So DOWICIL 200 can be considered compatible with almost any formulation from a pH standpoint. Moreover, the wide pH "window" offered by this preservative provides a margin of assurance in the event of moderate pH drift by the formulation.

Good with protein, surfactants, and parabens

Finally, DOWICIL 200 Preservative displays excellent compatibility with many common formulation ingredients. For example, its effectiveness is not diminished by relatively high concentrations of proteinaceous matter or sulfite-containing products. DOWICIL 200 retains its antimicrobial activity in the presence of anionic, nonionic and cationic formulation ingredients. Moreover, DOWICIL 200 displays excellent compatibility with parabens.

There are many good reasons to give DOWICIL 200 first consideration as you evaluate the compatibility of various preservative systems with your formulation.

But the question still remains: "Is DOWICIL 200 compatible with my formulations?" Only actual formulation testing can give a definitive answer. But the following list of product types that are successfully using DOWICIL 200 helps to illustrate its tremendous versatility.

Hair care products

conditioners
protein conditioners
herbal shampoo
conditioning shampoo
medicated shampoo
setting lotion
styling lotion
protein shampoo
aloe shampoo
finishing rinses
hair creams
hair rinses
texture lotion

Eye area products

mascara
eye shadow
eye color
eyeliner
creamy powder

Lotions

moisturizing lotion
body and skin lotions
cocoa butter lotion
cleansing lotion

Baby products

baby shampoo
baby powder
baby lotion
baby oil

Powders

blush
pressed powders
bath powder
dusting powders
talcum powders

Creams

skin cream
moisturizing cream
foot and hand cream
night cream
aloe cream
cold cream

Shaving products

shaving creams
shaving lotions
shaving gels

Suntanning products

suntan lotion
tanning accelerators
suntan oil
sunscreens

Raw materials

proteins
surfactants
shampoo base

Ethnic market products

hair moisturizers
hair dressings
hair conditioners
hair straighteners
styling mousses
curl activators
makeups

Miscellaneous

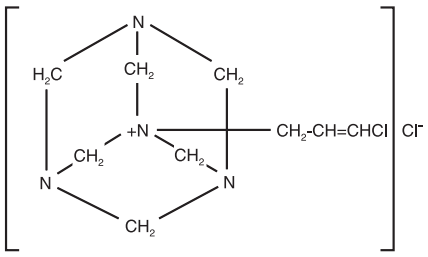
beauty masks
makeup base
waterless hand cleaners
scrub masks
bath preparations
corn silk
liquid hand soaps
liquid makeup

Physical Properties of DOWICIL 200 Preservative

(Laboratory results typical of the products; not to be considered specifications.)

DOWICIL 200 Preservative is a highly effective antimicrobial that has proven its effectiveness in numerous formulations in virtually every major cosmetic and personal care product category.

Figure 1 – Molecular Structure of DOWICIL 200 Preservative



Formula . . . . . .$C_6H_{12}N_4(CH_2CHCHCl)Cl$
CTFA Label Name Quaternium-15
Molecular Weight 251.2
Bulk Density lb/ft^3 . . . . . .25.0
CAS#: 51229-78-8

Sales Specifications

(Method of Analysis 24710a)
Description . . . . . .Off-white powder
Active ingredient† . . . . . .94% (minimum)
Color, Gardner
(2% aqueous solution) . . . . . .2 (maximum)
Sieve analysis:
Through No. 20
(U.S. Standard Sieve) 100%

†Cis isomer 1-(3-chloroallyl)-3,5,7-triaza-1-azonia-adamantane chloride

The fine powder form of DOWICIL 200 Preservative is hygroscopic. Therefore, shipping/storage containers must be kept closed (when not in use) to prevent caking and discoloration.

NOTE: Caking and discoloration do not impair antimicrobial properties, but may adversely affect the aesthetic appearance of end products.

Solubility

The solubility characteristics of DOWICIL 200 in common cosmetic ingredients are seen in Table 1. This table shows that DOWICIL 200 is highly soluble in water and has very low solubility in non-aqueous solvents. Little or no DOWICIL 200 Preservative migrates to the oil phase of a cosmetic product. Instead, it stays in the water phase, where it can be most effective against microorganisms.

Table 1 – Solubility of DOWICIL 200 in Common Cosmetic Ingredients

Solvent	In Grams/100 Grams of Solvent @ 25°C
Water	127.2
Methanol (anhydrous)	20.8
Propylene glycol, USP	18.7
Glycerine (99.5%)	12.6
Ethanol (absolute)	2.04
Isopropanol (anhydrous)	<0.1
Mineral Oil	<0.1

Solution pH

Fresh aqueous solutions of DOWICIL 200 have a pH of 4.5 to 5.5. After standing for several hours, these solutions will drift slightly and attain an equilibrium pH of 6.5 to 7.5.

Broad spectrum antimicrobial effectiveness

The function of a preservative is to prevent the growth of microorganisms. As the data in Table 2 show, DOWICIL 200 Preservative is highly effective against both bacteria and fungi.

The agar inhibition data in Table 2 are just a starting point. We've also run laboratory evaluations on many different types of cosmetic formulations. These tests consistently demonstrate that concentrations of DOWICIL 200 Preservative from 0.02 to 0.2% by weight maintain effective control after repeated insult.

Obviously, the most effective level of DOWICIL 200 should be determined for each formulation using appropriate testing procedures. That's the only way to precisely determine the antimicrobial activity of any preservative in a given formulation. Dow offers a 10-Cycle Challenge Test to assist in determining the effective level of preservative required for a formulation.

Table 2 – Antimicrobial and Antifungal Efficacy of DOWICIL 200 — Agar[1] Inhibition Data

Test Organism	Concentration (ppm) of DOWICIL 200 Required to Inhibit Growth
Bacteria	
Bacillus subtilis, ATCC 8473	60
Burkholderia cepacia, ATCC 25416	60
Citrobacter freundii, ATCC 43864	60
Enterobacter aerogenes, ATCC 13048	80
Enterobacter gergoviae, ATCC 33028	240
Escherichia coli, ATCC11229	100
Pseudomonas aeruginosa, ATCC 19429	320
Pseudomonas aeruginosa, ATCC 10145	240
Pseudomonas aeruginosa PRD10, ATCC 15442	160
Pseudomonas oleovarans, ATCC 8062	160
Staphylococcus aureus, ATCC 6538	60
Fungi	
Aspergillus niger, ATCC 16404	500
Candida albicans, ATCC 10231	250

[1]Bacterial tests were run with nutrient agar (Difco Laboratories); Fungal tests were run on malt agar (Difco) with added yeast extract.

How the Dow 10-Cycle Challenge Test is performed

How the Dow 10-Cycle Challenge Test is performed

One effective test method is the 10-Cycle inoculation-incubation procedure. We'll be glad to run the procedure on your formulation to help you evaluate DOWICIL 200. The following summary will familiarize you with the test method.

1) Samples are tested for sterility.
2) Each sample is inoculated with a 24-hour culture of mixed bacteria, followed by an incubation period lasting 24 hours. The samples are then streaked on nutrient agar. Both the samples and the agar plates are incubated for 48 hours, after which the plates are read for growth.
3) Allowing 24 hours between test cycles, step 2 is repeated for a total of ten inoculation-incubation cycles. The preservative is considered to provide adequate in-use antimicrobial activity only if no microbial contamination occurs during the ten test cycles.

This basic test procedure can also be performed with additional samples, using yeast or mold for inoculation, with appropriate changes in culture media, number of inoculations, temperature, and incubation time.

Advantages of the 10-Cycle Test procedure

The 10-Cycle Test method provides you with two fundamental benefits.

First, it's a repeated inoculation study involving a large number of insults. So it's a good simulation of the type of repeated exposure your formulation may be subjected to during manufacturing, shipping and consumer use.

Second, the Dow test is designed to reveal the level of preservative required to protect a specific formulation. That eliminates much of the guesswork from cost analysis and compatibility studies.

Put us TO THE TEST

Put unique Dow services and expertise to work in your formulation

Free formulation testing and additional lab services

Challenge testing of your formulation is a primary service offered free of charge by The Dow Chemical Company. We'll be glad to test the effectiveness of DOWICIL 200 in your formulation with our 10-Cycle Challenge Test.

We'll test your formulation with the levels of preservative you select. The results you'll get will tell you whether the levels you've chosen will adequately protect your formulation.

The information you obtain from Dow testing can be quite valuable, regardless of the size or sophistication of your operation. Our tests provide useful data that can dovetail with the results of separate tests. Getting started is as easy as picking up your phone and contacting your nearby Dow representative.

Dow knows cosmetic ingredients

When you work with Dow, you'll also enjoy the benefits of working with a major supplier of many other cosmetic and personal care product ingredients.

Ingredient materials produced by Dow include solvents, stabilizers, texturizing agents, aromatics, bases for creams and pastes, humectants, emollients, neutralizers, oxidizers, and thickening agents.

So if you have a question about the properties of a basic formulation ingredient, it's more than likely Dow can help.

Dow makes antimicrobials for more than just cosmetics

Our ability to provide formulators with technical assistance is also based on a comprehensive understanding of antimicrobials well beyond cosmetics.

Dow also manufactures antimicrobials for adhesives, paints, metalworking fluids, pulp and paper products, latex, waxes, cooling towers, disinfectants, cleaners, pet care products, and textiles, to name a few. You might be surprised to learn how many basic ingredients these water-based products have in common with cosmetics.

In addition, we produce low-persistence biocides for use in enhanced oil recovery systems and many types of circulating water systems.

Those applications probably don't relate directly to your specific situation, but they do speak for a pool of experience and diversity that's unique among suppliers of cosmetic preservatives.

Formulating with DOWICIL 200 Preservative

Here are some general guidelines for adding DOWICIL 200 Preservative to your formulations. Contact your Dow representative for assistance with specific formulations.

Preparing a Solution

A concentrated aqueous solution of DOWICIL 200 can be prepared by slowly adding the appropriate amount of powdered preservative to water in a 1:1 or 1:2 ratio, at a temperature below 45°C, and agitating until completely dissolved.

Adding DOWICIL 200 to Aqueous Formulations

The cosmetics formulator enjoys flexibility when adding DOWICIL 200 to products. Dow laboratory studies have shown that DOWICIL 200 can be incorporated into formulations by different methods – all resulting in equal preservative effectiveness.

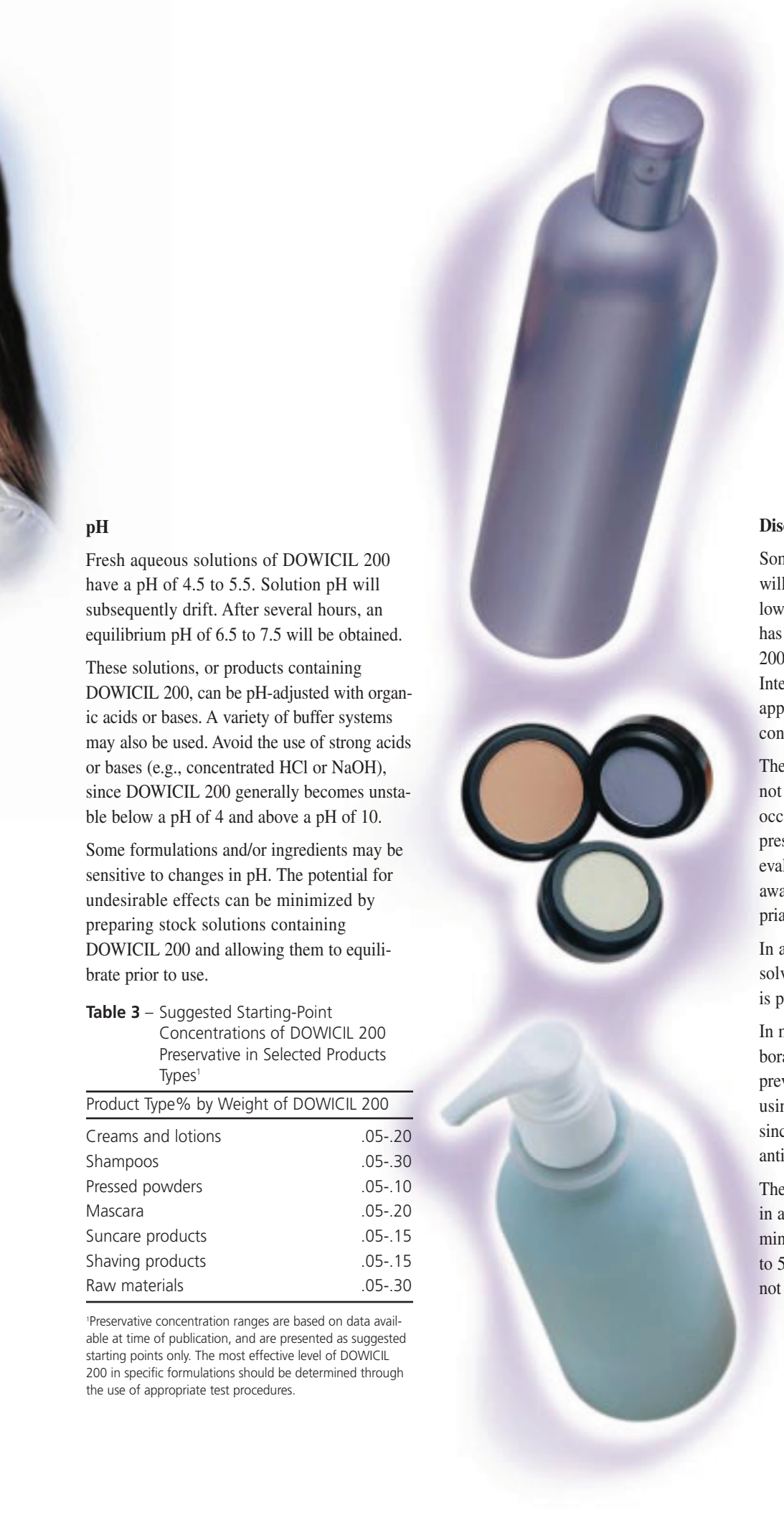
- DOWICIL 200 may be added either as a free-flowing powder or as a water concentrate to the final product. It's preferable to add DOWICIL 200 during the cooling phase, when formulation temperatures are below 50°C. If you must add the preservative to formulations at temperatures above 50°C, consult your Dow representative for assistance.
- It is often more convenient to add the antimicrobial to the water phase immediately before mixing it with the oil phase during the formulating process.

In any case, to obtain the maximum benefit of DOWICIL 200, the preservative should be added after any processing steps requiring prolonged elevated temperature (>50°C).

Adding DOWICIL 200 to Anhydrous Formulations

DOWICIL 200 is an ideal preservative for use in anhydrous formulations, as well. Its exceptionally high water solubility gives DOWICIL 200 the ability to eliminate the microbial contamination that may be present if small amounts of moisture are introduced into the product during use. Products such as mascaras, eye shadows, eyeliners, and pressed powders, for example, can be effectively preserved against repeated user contamination by grinding DOWICIL 200 into the color powder mix.

Although DOWICIL 200 has been incorporated into anhydrous formulations at temperatures exceeding 80°C without exhibiting loss of antimicrobial activity, formulators are urged to limit any exposure to elevated temperatures, and to consult with a Dow representative if desired.



pH

Fresh aqueous solutions of DOWICIL 200 have a pH of 4.5 to 5.5. Solution pH will subsequently drift. After several hours, an equilibrium pH of 6.5 to 7.5 will be obtained.

These solutions, or products containing DOWICIL 200, can be pH-adjusted with organic acids or bases. A variety of buffer systems may also be used. Avoid the use of strong acids or bases (e.g., concentrated HCl or NaOH), since DOWICIL 200 generally becomes unstable below a pH of 4 and above a pH of 10.

Some formulations and/or ingredients may be sensitive to changes in pH. The potential for undesirable effects can be minimized by preparing stock solutions containing DOWICIL 200 and allowing them to equilibrate prior to use.

Table 3 – Suggested Starting-Point Concentrations of DOWICIL 200 Preservative in Selected Products Types[1]

Product Type	% by Weight of DOWICIL 200
Creams and lotions	.05-.20
Shampoos	.05-.30
Pressed powders	.05-.10
Mascara	.05-.20
Suncare products	.05-.15
Shaving products	.05-.15
Raw materials	.05-.30

[1]Preservative concentration ranges are based on data available at time of publication, and are presented as suggested starting points only. The most effective level of DOWICIL 200 in specific formulations should be determined through the use of appropriate test procedures.

Discoloration

Some formulations containing DOWICIL 200 will demonstrate a slight to pronounced yellow discoloration. This occasional problem has been linked to a combination of DOWICIL 200 and fragrances that incorporate citral. Interestingly, the yellowing phenomenon apparently occurs in only a few systems containing this combination.

The advantages of using DOWICIL 200 need not necessarily be ruled out if yellowing occurs. In the event of incompatibility, the presence of citral in the fragrance should be evaluated. It is important for formulators to be aware of the phenomenon and to make appropriate tests for compatibility.

In addition, corrective measures may often solve compatibility problems even if citral is present.

In many instances, small quantities of sodium borate or sodium sulfite have been effective in preventing this discoloration. However, avoid using strong oxidizing or reducing agents, since these additives may adversely affect the antimicrobial performance of DOWICIL 200.

The propensity for DOWICIL 200 to discolor in any particular formulation can be determined simply by storing the formulation at 45 to 50°C for 48 hours. Discoloration should not be a factor if none occurs during that time.

Shelf Life of Concentrated Solutions

The antimicrobial activity of concentrated solutions of DOWICIL 200 gradually diminishes over time. For optimal preservative performance, do no store stock solutions longer than two weeks.

Shelf life in formulations

At the dilute levels (typically 0.02 to 0.2%) used in finished formulations, DOWICIL 200 Preservative remains highly effective for two or more years.

Using DOWICIL 200 in Combination with Other Antimicrobials

Challenge test results show that cost-effective concentrations of DOWICIL 200 provide excellent antimicrobial activity against even the most stubborn organisms. Combinations with methyl, propyl, and/or ethyl paraben at levels of 0.2 to 0.3% total parabens are sometimes used. Incorporation of EDTA at 0.05 to 0.1% may be useful in some cases as well.

The free formulation challenge testing service available from Dow can help you determine the most cost-effective level of DOWICIL 200 Preservative for achieving broad-spectrum antimicrobial performance in your specific system.

Packaging Considerations for Products Containing DOWICIL 200

No incompatibility problems are known to exist between DOWICIL 200 and commonly used packaging materials. However, to ensure that products formulated with DOWICIL 200 maintain maximum antimicrobial activity during subsequent storage and use, packaging material should be treated as a formulation ingredient for the purposes of compatibility testing.

Lab samples of DOWICIL 200

DOWICIL 200 Preservative is hygroscopic, and the small lab samples supplied to formulators may, as a result, begin to discolor and become caked after a few months. To avoid this, we suggest replacing lab samples of DOWICIL 200 every six months. Please contact your Dow representative to order replacement samples.

Comprehensive Testing Shows a Favorable Toxicologic Profile

Extensive animal as well as human studies have provided a comprehensive base of safety substantiation data on DOWICIL 200 Preservative. The results of these studies point to the conclusion that DOWICIL 200 has a favorable toxicologic profile. The material should present no serious handling, utilization or waste disposal problems when handled in accordance with the material safety data sheet and label instructions.

This section provides summary toxicologic information obtained from on-going Dow studies. Further information is available through your local Dow representative.

Eye

DOWICIL 200 Preservative, undiluted, is no more than slightly irritating to the eye. Direct contact with the eye may result in some discomfort and slight transient conjunctival irritation, which would be expected to subside promptly.

Ingestion

The single dose oral toxicity of DOWICIL 200 is low in all animal species tested, with the exception of rabbits. LD_{50} values were found to be as follows: male and female rats, 940-2664 mg/kg; mice,1310 mg/kg; male guinea pigs, 710 mg/kg; male chicks, 2800 mg/kg; female rabbits, 78 mg/kg.

Skin

As a dry powder or in solution (10%), DOWICIL 200 Preservative is, at most, slightly irritating to the skin. Stronger solutions and the powdered concentrate, moist and confined to the skin, can cause moderate skin irritation and possibly a burn.

As a dry powder, DOWICIL 200 is not absorbed through the skin in acutely toxic amounts. The material may be absorbed through the skin in harmful amounts if in strong solution or if the skin is irritated or abraded.

A study in pregnant rats showed no maternal or fetal toxicity nor any birth defects resulting from dermal application of DOWICIL 200 in a 50% aqueous solution at dose levels of 250 or 500 mg/kg/day.

Human skin studies

DOWICIL 200 was tested in human studies for skin irritation, skin fatiguing, sensitization and photosensitization properties. These tests were conducted with aqueous solutions of the preservative and with freshly made and aged prototype cosmetic formulations at use concentrations up to 0.75%. It was concluded that DOWICIL 200 Preservative is not a primary irritant, fatiguing agent, skin sensitizer or photosensitizer at concentrations up to 1%. Higher concentrations may be weak skin sensitizers in susceptible individuals.

NOTE: The toxicologic characteristics of DOWICIL 200 Preservative are a prime focus of continuing Dow studies. Information in addition to the summaries in this bulletin is available from your Dow representative.

These data substantiate the relative safety of DOWICIL 200 in cosmetics and personal care products. **However, we do not have knowledge of, or control over, customers' formulations or end products. Responsibility for adequate testing to establish safety of final products must be assumed by the cosmetics formulator.**

Discuss your needs and interests for further information with your Dow representative. Be certain to request the most current MSD sheet prior to handling or using DOWICIL 200.

Safe use and handling of DOWICIL 200 Preservative

These precautions are general in nature and are directed toward exposure to undiluted DOWICIL 200 Preservative or strong solutions (10% or more). Specific recommendations can be made only when specific handling conditions are known.

Handling

Observe reasonable precautions to avoid ingestion and skin contact, especially with strong (10% or more) aqueous solutions. Avoid contact with the undiluted material when the skin is wet, as with perspiration. Keep concentrated solutions or the dry powder of DOWICIL 200 away from cuts or wounds.

After working with DOWICIL 200, wash the hands and face well before eating or smoking. Remove grossly contaminated clothing as soon as possible and wash it before reuse. Wash contaminated skin with soap and a large quantity of water. Personnel working in a dusty atmosphere should shower and change clothing at the end of each work period.

Ventilation to control dusts below an exposure guideline of 1 mg/m^3 is recommended. If necessary, provide personnel with dust respirators and enforce their use. All personnel working with the product should wear clean, body-covering clothing. Use adequate eye protection, such as safety glasses. Locate any eye wash station reasonably close to personnel working with the product.

Storage

Keep DOWICIL 200 Preservative in closed containers, in a dry, cool area. To avoid decomposition, which will release smoke and flammable vapors, store below 120°F (49°C). Keep away from heat, sparks and open flame. Do not store DOWICIL 200 near flammable materials.

Disposal

Spills can be swept up. Use a floor sweeping compound, then flush the spill area with water to ground. Avoid contamination of public water supplies. Collected (swept-up) material can be disposed of either by burial or incineration in accordance with local regulations.

In disposal of any wastes, be certain all applicable federal, state and local regulations are met.

Thermal decomposition

DOWICIL 200 Preservative is an organic material that can undergo exothermic decomposition when the dry powder is exposed to elevated temperatures (>100°C).

Decomposition will take place with evolution of toxic, flammable vapors. If such decomposition occurs in a closed container, violent rupture of the container is possible.

Make fire fighters aware of possible hazards. They should use self-contained breathing apparatus if exposure to vapors is possible. Extinguish fires involving DOWICIL 200 with water fog.

Customer Notice

Dow encourages its customers to independently review their applications of Dow products from the standpoint of human health and environmental quality. It is important that each customer ensure that Dow products are not used in ways for which they are not intended or tested. For specific information, refer to the current material safety data sheet for DOWICIL 200.

For more information about DOWICIL 200 Preservative:

From the U.S. and Canada	call 1-800-447-4369
From Mexico	call 95-880-447-4369
In Europe	call +31/20.691.6268 fax +31/20.691.6418
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