

Product Information

Glydant™ Plus Liquid

The high performance liquid preservative system.

Synergistic, broad spectrum mode of action: no need for auxiliary preservatives.

Highly cost-effective use level.

Stable in sunlight and over a wide range of temperatures and pH.

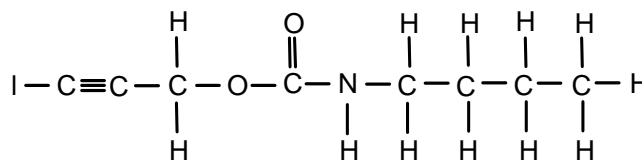
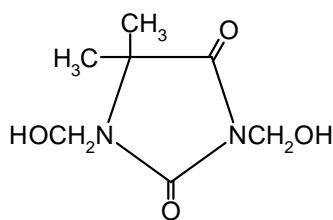
Water soluble.

Low free formaldehyde and improved toxicology profile.

Compatible with virtually all raw materials used in personal care formulations.

1. Active matter

Equilibrium mixture in water of 1,3-Dimethylol-5,5-dimethylhydantoin and 3-Iodo-2-propynyl butyl carbamate



1.1	CAS No.:	not applicable (mixture)
1.2	EINECS No.:	all the components of the mixture are listed in EINECS
1.3	UN No.:	3082
1.4	INCI-Names (actives):	DMDM Hydantoin (and) Iodopropynyl Butylcarbamate

2. Specifications

2.1	Color, APHA	50 max.
2.2	Free HCHO	0.09 % max.
2.3	Total HCHO	13.0 % min.
2.4	IPBC	2.2 – 2.8 %
2.5	pH	6.0 – 8.0
2.6	Water content	22.0 – 26.0 %
2.7	Clarity	Pass (clear)

3. Properties

3.1	Appearance	Water white liquid
3.2	Hydantoin	70.0 % (patented, proprietary equilibrium mixture of hydantoin species)
3.3	Butylene glycol	~4.5 %
3.4	Specific gravity at 25°C	~1.1992
3.5	Flash point	> 93°C
3.6	Solubility	see § 9.1
3.7	Compatibility	see § 9.2

4. Registration

4.1 IPBC-Registration

North America:

IPBC was reviewed in 1996 by the Expert Panel of the Cosmetic Ingredient Review (CIR) and their recommendations were adopted by CTFA. Their approval states that IPBC can be used at a level up to 0.1 % of the formulation in both rinse-off and leave-on products. The only restriction is that IPBC is not to be used in aerosol products.

Europe:

On April 17, 2007 the European Commission put into force an amendment to the existing entry 56 to Annex VI allowing the following for IPBC:

- 0.02 % in rinse off and 0.01% in leave-on products, except in deodorants/antiperspirants where the maximum concentration is limited to 0.0075 %.
- IPBC may not be used in oral and lip products and there are additional restrictions for children's products and required warnings.
- Not to be used in preparations for children under three years of age, **except in bath products/shower gels and shampoo.**
- Please also note labelling requirements listed on the directive regarding use on children under the age of three:

Rinse-off products:

Solely for products, other than bath products/shower gels and shampoo, which might be used on children under three years of age: "Not to be used for children under three years old."

Leave-on products:

Solely for products which might be used on children under three years of age: 'Not to be used for children under three years of age'.

- Not to be used in body lotion and body cream. Concerns any products aimed to be applied on a large part of the body.

The commission requires that all products in the cosmetic markets comply with this directive by October 18, 2008.

Japan:

Lonza has received approval from Japan MHLW for IPBC preservatives in Cosmetics and Personal care products under Pharmaceutical and Food Safety Bureau Notification N°0524001.

The approved usage level of IPBC for both rinse-off and leave-on products is 0.02% which includes lip care, oral care and baby care products, with the exception of aerosolized formulations

4.2 DMDMH-Registration

Europe	listed as a preservative for cosmetics on the EEC positive list EEC max. accepted concentration: 0.6 % (100% active)
USA	DMDM Hydantoin is recognized by the Cosmetic, Toiletry and Fragrance association (CTFA) for use in cosmetic and personal care products.
Japan	DMDM Hydantoin can be used at a level up to 0.3% only in products that are rinsed after use. Listed in the positive list However, the following warning must be labeled: "should not be used by infants or by people who are hypersensitive to formaldehyde."

	leave-on products	rinse-off products	deodorants and antiperspirants
Glydant™ Plus	0.2%	0.4%	0.15%
Glydant™ Plus Liquid	0.4%	0.8%	0.3%

Not to be used in body lotion and body cream . Concerns any products aimed to be applied on a large part of the body

Cannot be used in oral hygiene or lip care products.

4.4 Additional restrictions for children's products and required warnings.

Not to be used in preparations for children under three years of age, **except in bath products/shower gels and shampoo**

Please also note labelling requirements listed on the directive regarding use on children under the age of three:

Rinse-off products :Solely for products, other than bath products/shower gels and shampoo, which might be used on children under three years of age: "Not to be used for children under three years old."

Leave-on products :Solely for products which might be used on children under three years of age: 'Not to be used for children under three years of age'

5. Antimicrobial efficacy

Efficacy in Challenge Tests

Glydant™ Plus Liquid was incorporated into a shampoo formula and a glyceryl monostearate cream (GMS), both standard media used for efficacy studies.

Shampoo formula		GMS cream	
Ingredients (unpreserved)	% wt/wt.	Ingredients (unpreserved)	% wt/wt.
Sodium lauryl ether sulfate	35.0	Glyceryl monostearate	6.0
Triethanolamine lauryl sulfate	25.0	POE 20 glyceryl monostearate	4.0
Cocamide DEA	3.0	Cetearyl alcohol	1.5
Anhydrous protein	1.0	Myristyl propionate	8.0
Sterile DI water	36.0	Glycerin	5.0
Total weight	100.0	Sterile DI water	75.5
		Total weight	100.0

% preservatives (as supplied) required to achieve < 10 cfu/g of mix inocula in the GMS cream

	Glydant™ Plus Liquid	Competitor A	Competitor B	Competitor C	Competitor D
BACTERIA ¹					
Day 7	0.15	0.2	0.3	> 0.6	> 0.8
Day 14	0.15	0.2	0.4	> 0.6	< 0.8
Day 21	0.15	0.2	0.3	> 0.6	< 0.8
Day 28	0.15	0.2	0.3	> 0.6	< 0.8
FUNGI ²					
Day 7	0.2	> 0.8	> 0.8	> 0.6	> 1.0
Day 14	0.2	0.8	> 0.8	> 0.6	> 0.8
Day 21	0.2	0.8	> 0.8	> 0.6	> 0.8
Day 28	0.2	0.8	> 0.8	> 0.6	> 0.8

% preservatives (as supplied) required to achieve < 10 cfu/g of mix inocula in the Shampoo

	Glydant™ Plus Liquid	Competitor C	Competitor D
BACTERIA ¹			
Day 7	0.1	NT	NT
Day 14	0.1	NT	NT
Day 21	0.1	NT	NT
Day 28	0.1	NT	NT
FUNGI ²			
Day 7	0.1	> 0.6	> 0.8
Day 14	0.1	> 0.6	> 0.8
Day 21	0.1	> 0.6	> 0.8
Day 28	0.1	> 0.6	> 0.8

¹ Mix inoculum of bacteria consists of *E.coli*, *P.aeruginosa* and *S.aureus*.

² Mix inoculum of fungi consists of *C.albicans* and *A.niger*.

NT = Not Tested

Competitor A : commercially available blend containing 60% Propylene Glycol + 39.6% Diazolidinyl Urea + 0.4% IPBC.

Competitor B : commercially available blend containing 56% Propylene Glycol + 30% Diazolidinyl Urea + 11% Methylparaben + 3% Propylparaben.

Competitor C : 0.4% Methylparaben + 0.2% Propylparaben.

Competitor D : commercially available blend containing 70% Phenoxyethanol + 15% Methylparaben + 5% Isopropylparaben + 5% Isobutylparaben + 5% Butylparaben.

5.1 BACTERIA

MIC values

Micro-organisms	ppm Glydant™ Plus Liquid as supplied
Acinetobacter baumannii	125
Pseudomonas cepacia	188
Klebsiella pneumoniae	188
Staphylococcus epidermidis	188
Escherichia coli	250
Staphylococcus aureus	375
Enterobacter gergoviae	500
Pseudomonas aeruginosa	500

5.2 FUNGI + YEAST

MIC values

Micro-organisms	ppm Glydant™ Plus Liquid as supplied
Aspergillus niger	48
Trychophyton mentagrophytes	48
Candida albicans	250
Saccharomyces cerevisiae	250

6. Other investigations

Typical formulations containing Glydant™ Plus Liquid and other preservatives have been undergoing comparative tests (28 days challenge tests and MIC determinations). Information with results available upon request.

7. Stability

7.1 Recovery % of actives vs. Temperature

Time, months	% total HCHO			% IPBC		
	23°C	40°C	50°C	23°C	40°C	50°C
1	100	100	100	100	100	> 90
3	100	> 95	NT	> 90	> 95	NT
12	> 95	NT	NT	> 95	NT	NT
18	> 95	NT	NT	> 90	NT	NT

NT: not tested

7.2 Typical % Free HCHO level

	% Free HCHO
Glydant™ Plus Liquid	< 0.1
Competitor A	> 1.0
Competitor B	> 1.0

7.3 Color stability

Water-white color of Glydant™ Plus Liquid is stable when stored at 23°C.

7.4 Homogeneity stability

Glydant™ Plus Liquid homogeneous phase is stable when stored at 23°C.

After storage of three months at 40°C, one month at 50°C and three months exposure to sunlight, Glydant™ Plus Liquid maintains its homogeneity.

8. Use areas

Hair Care	Shampoos, Conditioners, Rinses
Baby Products	Shampoos, shower gels and bath products
Shaving	Lotions, Creams, Gels
Eye makeup	Mascara, Eye Shadow, Eye Liner
Creams	Hand and Foot and Face
We do not recommend the use of Glydant™ Plus Liquid in aerosol products.	

9. Heavy metal content

Sample N° Batch Nr. G9439769

µg/g Co	< 0,5 ppm
µg/g Cr	< 0,5 ppm
µg/g Ni	< 0,5 ppm
µg/g As	< 0,5 ppm

Cr results confirmed via ICP/OES

10. Recommendations to formulate

It can be added at both room and elevated temperatures as high as 60°C for 2-3 hours. However, at high temperatures, mixing should be carried out in a closed vessel.

Glydant™ Plus Liquid is stable over a wide range of pH (3-10)

10.1 Solubility

Glydant™ Plus Liquid is readily soluble in any aqueous phase, as well as in polar organic solvents like alcohols, glycols, glycol esters, alkyl sulfates, amphoterics, alkanolamides...

10.2 Compatibility

It is compatible with virtually all raw materials used in personal care formulations including anionic, cationic and nonionic surfactants, thickening agents, chelating agents, colors and fragrances. A stability study has been conducted by adding 0.3% Glydant™ Plus Liquid in a broad variety of personal care products, and by checking viscosity, pH, color and homogeneity of the end products after 1 month at room temperature and 50°C. Glydant™ Plus Liquid proved to be compatible with all the tested products : no major change was observed for either criteria.

11. Analytical procedure

Analytical methods to determine free and total formaldehyde of Glydant™ Plus liquid and formulated products are available upon request.

HPLC to determine IPBC in Glydant™ Plus Liquid.

12. Packaging / Storage

Product is supplied in polyethylene pails holding 18.14 kgs net or polyethylene drums holding 226.8 kgs net. It can be stored 18 months in the sealed original packaging, preferably at a temperature between 15 and 24°C. The product must be kept protected from light and freezing.

13. Regulatory information
refer to MSDS

14. Toxicological information
refer to MSDS

15. Ecological and Ecotoxicological Information
refer to MSDS

16. Safety evaluation

	DMDMH Hydantoin	3-Iodo-2-propynyl butylcarbamate
Sensitizer	no	no
Nitrosamines	no	no
Teratogenic	no	no
Mutagenic	no	no
Genotoxic	no	no

Evaluations of DMDM Hydantoin and 3-Iodo-2-propynyl butylcarbamate clearly show that there are no adverse toxicological effects associated with either component.
Additional tox data are available upon request