

Technical Data

MPDiol® Glycol

Clinical Dermal Studies

Cumulative Dermal Irritation Study

A 14-day cumulative dermal irritation study was conducted on 25 human volunteers with the five materials listed below. Approximately 0.2 ml of each test material was applied neat and as a 50% aqueous solution. Each material was applied to the ¾" X ¾" gauze portion of an adhesive dressing. When secured to the skin sites, these dressings formed occlusive patches. Each test material was applied to the skin site Monday through Friday. Patches applied on Friday remained in place until the following Monday. The test sites were evaluated for irritation prior to each patch application and at the end of the study.

MPDiol Glycol

None of the subjects tested with neat material or a 50% aqueous solution exhibited any reactions.

1,3 Butylene Glycol

None of the subjects tested with neat material or a 50% aqueous solution exhibited any reactions.

Propylene Glycol USP

Five subjects exhibited a minimal response (+1) to neat propylene glycol USP (PG USP) after the first patch and one of these subjects also had a minimal response after the second patch. None of these five subjects exhibited further response throughout the remainder of the study. Another subject exhibited a minimal reaction after the first patch and a marked reaction (+3) on day 2. This individual was excluded from further testing with neat propylene glycol. None of the subjects, including the subject that had a marked reaction to neat PG USP, reacted to the 50% aqueous PG USP solution. There was no indication that PG USP caused cumulative dermal irritation.

Dipropylene Glycol – Fragrance Grade

One subject exhibited minimal reactions (+1) after the first 4 patches with neat test material. However, this subject did not exhibit further reactions throughout the remainder of the study. A minimal response (+1) was noted in one subject only after the first patch with the 50% aqueous dipropylene glycol solution. There was no indication that dipropylene glycol caused dermal cumulative irritation.

Tripropylene Glycol

None of the subjects tested with neat material or a 50% aqueous solution exhibited any reactions.

Control – Water

There were no reactions to the vehicle control.

Repeated Insult Patch Test

Approximately 0.2 ml of MPDiol glycol was applied as occlusive patches to the upper backs of 110 human volunteers. During the induction phase of this test, MPDiol glycol was applied to the skin three times per week for a total of ten patch applications. The patches remained in contact with the skin for 24 hours with evaluations of the skin sites made prior to the reapplication of the patches.

Approximately two weeks after the removal of the last induction patch, a challenge patch was applied to the original site and to a previously untreated skin site (virgin site). The challenge patches were removed after 24 hours. The skin sites were evaluated immediately after removal of the patches (24-hour post application), 48 hours post-application, and at 72 hours post-application for any subject exhibiting a reaction during the previous challenge evaluations.

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During the induction phase, four subjects exhibited sporadic mild skin reactions. One additional subject exhibited a moderate reaction after the second patch, and the patch was moved to an adjacent site. This subject continued to show mild skin reactions only in the induction phase of the study.

After the challenge application, five subjects exhibited a mild to moderate dermal response on the original and/or virgin site. One of the responses was questionable because a mild score was noted only on one skin site at 48 hours and no responses were present at 72 hours or at re-challenge. The other subjects exhibiting reactions at 24 and/or 48 hours also responded at 72 hours and to a re-challenge phase one week later.

Three individuals exhibiting dermal responses to MPDiol glycol were later challenged with 1,3-butylene glycol and propylene glycol. Two of these subjects also exhibited mild to moderate responses to 1,3-butylene glycol and to propylene glycol. The subject that exhibited a questionable response during the original challenge to MPDiol glycol showed no skin reactions to either 1,3-butylene glycol or propylene glycol.

Commercial cosmetic formulations containing MPDiol glycol as an ingredient, with CTFA name "Methyl-propanediol", are being developed. For example, a deodorant formulation containing MPDiol glycol as the major ingredient was evaluated for dermal irritation potential. In clinical tests simulating use conditions, dermal responses similar to those seen with conventional stick deodorants containing other glycols were observed. Currently, this product has been successfully marketed for over a year.

Other Information Handling

This information is believed to be accurate as of the date of publication. It is the sole responsibility of the customer to determine whether the product is appropriate and suitable for the customer's specific use. Specific end uses may require approval by appropriate regulatory agencies. Lyondell Chemical Company makes no warranties, express or implied, regarding the product or information contained therein. The applicable Material Safety Data Sheet should be reviewed by customer before handling the Lyondell Chemical product. Lyondell Chemical Company disclaims any liability for infringement of any patent by reason of customer's use of any Lyondell Chemical Company products in combination with other materials or in any process.

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