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Toxicology / Regulatory / Health, Safety & Environmental Studies of Pemulen™* Polymeric Emulsifiers

Effect of Microbial Activity

Pemulen™ polymeric emulsifiers do not support bacterial or fungal growth. Pemulen™ polymers do not, however, prevent the growth of bacteria or fungus associated with nutrients found in normal water systems. Pemulen™ polymers are compatible with most commonly used preservatives.

Biotreatability of Pemulen™ Polymers

The environmental fate of chemicals is increasingly becoming a concern of consumers and responsible chemical producers and formulators. For chemicals found in products that are disposed "down the drain," it is important they do not pass through the municipal waste treatment facility into lakes and rivers. To prevent this, such chemicals may either be biodegraded or removed during the normal wastewater treatment.

This section is designed to answer three questions about Pemulen™ polymers:

1. Are these polymers biodegradable?
2. Do they inhibit or harm the bacteria found in treatment facilities?
3. Are they removed during normal wastewater treatment?

Biodegradability of Pemulen™ Polymers

Biological oxygen demand tests were performed on a Pemulen™ crosslinked polyacrylic acid polymer (Dr. Brian Arbuckle, University of Akron, April 16, 1992). The biological oxygen demand (BOD) was zero. In essence, the same characteristics which give these polymers excellent shelf life in severe environments also prevent them from degrading in a wastewater treatment facility.

Inhibition of Bacteria by Pemulen™ Polymers

During the above BOD testing, the effect of Pemulen™ polymers on bacteria was examined. In the concentrations tested (0.85, 1.7, 8.5, 17 and 42 mg/L), this work found none of the polymers to be inhibitory to the bacteria typically found in a wastewater treatment facility. Thus, while these polymers are not degraded, they neither harm the bacteria nor render it less effective.

Removal of Pemulen™ Polymers in a Treatment Facility

If Pemulen™ polymers are not degraded in a typical wastewater treatment facility, they must be removed in some fashion or else they would pass through to the environment. Tests were performed (Dr. Brian Arbuckle, University of Akron, April 16, 1992) to determine if the polymers would be removed during typical wastewater treatment by sorption onto the biomass. (When the term sorption is used, it usually means either a physical adsorption or absorption on the solid. It is also possible that material could be trapped in the biological floc and therefore be removed by that mechanism. Sorption will be used here to indicate removal, not necessarily the mechanism.)

The tests were performed at significantly higher concentrations of polymer than would be expected in real life (two to three orders of magnitude greater). This was done so the polymer could be detected analytically, but also results in a more severe test than would be expected in an actual municipal wastewater treatment situation. A

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standard U.S. EPA Synthetic Waste Recipe[1] was used and mixing times representative of typical municipal treatment facilities were employed.

The above tests show that, within experimental test sensitivity, Pemulen™ polymers are completely sorbed or trapped onto the biomass at polymer concentrations up to 16 ppm. Thus, instead of passing through to lakes and streams, these polymers are removed with the biomass and disposed or incinerated.

Conclusions

Based on the above testing, it can be said that Pemulen™ polymers:

- are not biodegradable,
- do not inhibit waste treatment bacteria, and
- do not pass through typical wastewater treatment to the environment, but are instead removed with the biomass.

Toxicology Studies

The toxicology studies summarized below were performed on Pemulen™ polymeric emulsifiers.

Skin Irritation

The potential irritant and/or corrosive effects of Pemulen™ were evaluated on New Zealand white rabbits. Each of six rabbits received a 0.5g dose of the test article as a dermal application to both an intact and an abraded test site. The dose was held in contact with the skin under a semi-occlusive binder for an exposure period of 24 hours. Following the exposure period, the binder was removed and the remaining test article was wiped from the skin using gauze and distilled water. Test sites were subsequently examined and scored for dermal irritation for up to three days following patch removal.

A very slight erythema was observed on the majority of intact and abraded test sites at the 25-hour scoring interval. By 72 hours, all dermal responses had resolved.

Under the test conditions, Pemulen™ polymeric emulsifiers would be considered to have a negligible irritation potential. The calculated Primary Irritation for Pemulen™ was 0.42 (maximum possible score 8.0).

Eye Irritation

The potential eye irritant and/or corrosive effects of Pemulen™ polymeric emulsifiers were evaluated in New Zealand White rabbits. Each of nine animals received a 0.021 g dose (0.1 ml equivalent) of the test article (i.e., neat powder) in the conjunctival sac of the right eye. The contralateral eye of each animal remained untreated and served as a control. At 30 second postinstillation, both eyes of three rabbits were rinsed with 50 ml of physiological saline (rinse group); no rinsing procedure was utilized on the six remaining rabbits (no rinse group). Test and control eyes were examined for signs of irritation for up to 72 hours following dosing.

In the no rinse group, exposure to the test article produced significant ocular irritation in 3/6 test eyes. Corneal opacity (3/6 eyes) and iritis (1/6 eyes) was observed at the 24 hour scoring interval and resolved completely by 72 hours. Minimal conjunctivitis (conjunctival redness and swelling) was observed in 6/6 test eyes at 24 hours postdose and completely resolved by test termination (72 hours).

In the rinse group, exposure to the test article produced generally less severe responses than that noted in the no rinse group. Iritis was observed in 1/3 eyes at 24 hours and diminished completely at 48 hours. Conjunctivitis was observed in 3/3 eyes at 24 hours and diminished by test termination in 2/3 eyes.

Based on the no rinse test data, Pemulen™ is considered to be a borderline irritant to the ocular tissue of the rabbit according to the FHSA evaluation criteria.

[1] Barth, E.F., et al., "Biodegradation Studies of Carboxy-methyl Tartonate," In-house U.S. EPA report, (1978), U.S. EPA contact: Henry Tabak

Human Patch Test

The skin irritation and/or sensitizing potential of Pemulen™ polymeric emulsifiers was evaluated by the intensified version of the Shelanski and Shelanski Human Repeated Insult Patch test.

Pemulen™ was impregnated into strips of surgical gauze which were then cut into 1" x 1" squares. For each application, a patching device containing one of these squares on its webril pad was moistened and positioned directly on a designated site on the back of each subject with the gauze square in contact with the skin.

Pemulen™ produced no visible effects in 43 of 54 subjects during the primary irritation/activation test period. Faint or moderate reddening (erythema) occurred once in 9 subjects and twice in 2 subjects. These effects would put Pemulen™ in the category of a very weak skin irritant.

Three of 53 subjects had solitary episodes of faint erythema during the challenge phase. The absence of responses significantly different than those obtained during the initial test phases indicates that Pemulen™ does not possess a skin-sensitizing potential which can attain clinical status under the test conditions.

It was concluded that the results of this test furnish no basis for contraindicating skin contact with Pemulen™ polymeric emulsifiers under similar or less stringent conditions than those used in this test.

Global Inventory Status

The CAS numbers for Pemulen™ polymers are considered proprietary information. Their status on the various worldwide chemical inventories is described below:

Chemical Inventory	**Pemulen™**
United States TSCA	Yes
Europe Economic Community EINECS	Yes*
Canada DSL	Yes
Japan MITI	Yes
Australia AICS	Yes
Korea KICS	Yes

**These products are polymers. EINECS does not list polymers, only monomers. The monomers in these products are listed on EINECS.*

Agricultural Clearances

U.S. EPA has granted exemptions from the requirement of a tolerance for pesticide formulations under 40 CFR 180.1001(c), "--as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest", and 180.1001(e), "--as inert (or occasionally active) ingredients in pesticide formulations applied to animals".

Heavy Metals
Pemulen™ polymers are in compliance with all CONEG Model Toxics Legislation; Pemulen™ polymers do not exceed 100 parts per million by weight of lead, cadmium, mercury or hexavalent chromium. To the best of our knowledge, Pemulen™ polymers do not contain arsenic, barium, cadmium, chromium, copper, lead, mercury, nickel, selenium, silver or zinc. Lubrizol Advanced Materials, Inc. does not:

- use any of these heavy metals in the manufacture of Pemulen™ polymers.
- expect any of these chemical substances to be produced as a result of our manufacturing processes, or
- routinely test for the presence of these substances (due to the first two responses).

Periodic testing has indicated the following (under the following detectable limits):

Pb	<0.1 ppm
Hg	<0.5 ppm
Sb	<0.5 ppm
Cd	<0.5 ppm
Ni	<1.0 ppm
Total heavy metals (As lead)	<20 ppm

Ozone Depleting Substances (ODS)
According to the definitions provided in the final ruling published as 40 CFR part 82 on February 11, 1993, Pemulen™ polymers do not contain, nor are manufactured with ozone depleting chemicals.

ISO 9000 Registration
The Pemulen™ polymer manufacturing location has achieved ISO 9002 registration. ISO 9000 is a system for establishing, documenting and maintaining a system for ensuring the quality of the results of a manufacturing process.

Chemical Manufacturers Association (CMA)
Lubrizol Advanced Materials, Inc. is a member of the CMA. As a member, Lubrizol, Inc. has firmly adopted the Responsible Care Initiative. This Initiative is the most ambitious and comprehensive environ-mental improvement effort ever attempted by an American industry.

Responsible Care commits all members to two critical elements:

- to continually improve performance in the areas of health, safety and environmental quality, and

- to work with the local communities to elicit and respond to public concerns about products and operations.

Lubrizol Advanced Materials, Inc. ensures that its chemical products are designed, manufactured, marketed, distributed, stored, used and/or disposed of safely without adverse affect to human health or the environment.