STATE OF MINNESOTA

COUNTY OF RAMSEY

MINNESOTA POLLUTION

CONTROL AGENCY

In the Matter of the Proposed Amendment of Rules Governing the Regulation of High pH Hazardous Waste Which is Reused or Recycled, Minn. Rules Parts 7045.0125 and 7045.0142

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

The subject of this proceeding is the revision of rules of the Minnesota Pollution Control Agency (hereinafter "Agency") governing the management of hazardous waste by beneficial use, reuse, recycling or reclamation, Minn. Rules pt. 7045.0125 (1984), and the adoption of a new rule establishing a procedure for determining whether a waste with a pH above 12.5 will cause dermal irritation, Minn. Rules pt. 7045.0142. These rules are proposed for amendment pursuant to the Agency's authority under Minn. Stat. § 116.07, subd. 4 (1984).

The proposed amendments to the Agency's rules set forth the management requirements applicable to a waste which is hazardous solely because it has a pH greater than 12.5, does not contain a listed waste, does not exhibit any other characteristic of a hazardous waste, is not a sludge as defined in 40 C.F.R. § 260.10, is not a primary irritative substance and is to be beneficially used, reused, recycled or reclaimed. The proposed amendments also establish the procedure to be used to determine if the waste is a primary irritative substance.

This Statement of Need and Reasonableness is divided into several parts. Part II contains the Agency's explanation of the need for the proposed amendments. Part III contains the Agency's explanation of the reasonableness of the proposed amendments. Pursuant to the requirements of Minn. Stat. § 14.115 (1984), Part IV documents how the Agency has considered the methods of reducing the impact of the proposed amendments on small businesses. Part VI contains a list of the exhibits relied on by the Agency to support the proposed amendments. The exhibits are available for review at the Agency's offices at 1935 West County Road B-2, Roseville, Minnesota 55113.

II. NEED FOR THE PROPOSED AMENDMENTS TO THE HAZARDOUS WASTE RULES

Minn. Stat. ch. 14 requires an agency to make an affirmative presentation of facts establishing the need for and reasonableness of the rules or amendments proposed. In general terms this means that an agency must set forth the reasons for its proposal and the reasons must not be arbitrary or capricious. However, to the extent that need and reasonableness are separate, need has come to mean that a problem exists which requires administrative attention and reasonableness means that the solution proposed by the agency is appropriate.

Need is a broad test that does not easily lend itself to an evaluation of each proposed revision. In this broad sense the need for amendments to the Agency's rules governing the management of hazardous waste by reuse or recycling arises as a result

of information received by the Agency that Minnesota's stringent rules regarding recycling and reuse of hazardous wastes may inappropriately restrict the management options available for certain wastes.

In particular, a reuse/recycling market exists for wastes which are classified by Minn. Rules pt. 7045.0131, subp. 4, as hazardous only because the pH exceeds 12.5. Such wastes may be neutralized and when neutralized do not present any significant hazard to public health or welfare or the environment. For example, a calcium sulfate slurry, which is a hazardous waste only because the pH is greater than 12.5, is produced in an alkali processing plant in California. This slurry is dried and the solids remaining are sold as agricultural gypsum for soil conditioning. High pH wastes also have an application as an additive for neutralizing the acidic scrubber solution produced in flue gas desulfurization systems.

The Agency has been informed however, that subjecting such wastes to manifesting and other pretransport requirements when they are to be reused or recycled increases the possibility that these wastes will be disposed of rather than reused because the cost of disposal may be less than the cost of recycling the waste. Disposal is the least desirable management option for hazardous waste. Whenever there is a choice between disposing of hazardous waste and managing that waste to avoid disposal, the latter option should be chosen. Experience has shown that

hazardous waste disposal facilities have presented risks to the environment. For example, many of the sites being cleaned up under state and federal "Superfund" laws, are sites where hazardous and other wastes were disposed of in the past. Many of these sites were permitted as disposal facilities and at the time of permitting were considered to be state of the art facilities. Moreover, information is now coming in that some of the facilities to which waste from these "Superfund" sites is being sent are leaking. Disposal capacity at permitted hazardous waste facilities is limited. To the extent it can be encouraged without presenting any hazard to human health, welfare or the environment, the beneficial use, reuse, recycling and reclamation of hazardous waste should be encouraged.

The proposed amendments reduce the requirements applicable to certain high pH wastes which are to be reused or recycled. Such reduced requirements are needed to promote recycling and discourage disposal.

III. REASONABLENESS OF THE PROPOSED AMENDMENTS TO THE HAZARDOUS WASTE RULES

The Agency is required by Minn. Stat. ch. 14 to make an affirmative presentation of facts establishing the reasonableness of the rules or amendments proposed. Reasonableness is the opposite of arbitrariness and capriciousness. It means that there is a rational basis for the Agency's action.

As discussed above, strict regulatory control of the manage-

ment of selected hazardous wastes which have a beneficial reuse market may discourage recycling and present a significant disposal problem. Minnesota's rules governing the recycling of hazardous waste are more stringent than the corresponding federal regulations. Under the federal regulations, most waste which is to be beneficially reused or legitimately recycled is exempt from regulation. Minnesota's rules do not exempt hazardous waste destined for recycling from regulation. Rather, the rules specify which requirements must be met based on the type of hazardous waste, the process involved in reuse, or recycling of the waste, and the ability of the waste to damage human health or the environment if the waste is mismanaged.

Under both Minnesota rules and federal regulations a waste is classified as a hazardous waste either due to the fact that it exhibits one or more characteristics, or because it is a listed hazardous waste. Among the characteristics which make a waste hazardous is corrosivity. This characteristic is determined either by a pH test, or a steel corrosion test. Based on the pH test, a waste having a pH greater than 12.5 is a hazardous waste. Minn. Rules pt. 7045.0131, subp. 4. The pH test provides an indicator as to the waste's properties; however, it does not actually test the waste's ability to act as a corrosive substance.

Agency staff have evidence which shows that some wastes which have a pH greater than 12.5 do not cause dermal irritation. See Exhibit 4. This means that while the waste is classified as

hazardous, it does not act as a corrosive substance. As discussed above, a commercial market exists for the reuse of high pH waste which is classified as hazardous only because of the high pH. It is therefore reasonable to subject this waste to fewer regulatory requirements if it is to be beneficially reused or recycled. The proposed rules are reasonable because they relax certain management requirements for a readily recycled hazardous waste which presents a minimal hazard to the public health while retaining sufficient requirements to insure that the waste is being properly managed.

Minn. Rules pt. 7045.0125 provides that a hazardous waste that is to be beneficially used, reused or legitimately recycled or reclaimed is exempt from the the management requirements for hazardous waste and from the Agency's permitting requirements except as specified in the rule. Subpart 2, Items A - E set forth the management requirements applicable to various types of wastes which are to be reused or recycled. The Agency is proposing to amend Subpart 2 of Part 7045.0125 to add a new item F which will set forth the requirements for certain high pH wastes which are to be reused or recycled.

Under the proposed new Item F, to qualify for these reduced requirements the waste must have the following characteristics. First, the waste must not be a sludge as defined in 40 C.F.R. § 260.10 (1984). 40 C.F.R. § 260.10 (1984) defines "sludge" as solid, semi-solid, or liquid waste generated from a municipal,

commercial, or industrial wastewater treatment plant, water supply treatment plant, or air pollution control facility exclusive of the treated effluent from a wastewater treatment plant. The requirements applicable to the reuse or recycling of wastes which meet the federal definition of sludge are set forth in Minn. Rules pt. 7045.0125, subp. 2, items C. and E., and are at least as stringent as the corresponding federal requirements. The proposed requirements for high pH wastes are less stringent than those applicable to wastes which meet the federal definition of a sludge. Since Minnesota has received final authorization for its hazardous waste program pursuant to the Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901 et seq., the Agency's rules must be at least as stringent as the federal regulations. Therefore, it is reasonable and necessary that this new provision not apply to wastes meeting the federal definition of a sludge.

Second, the waste cannot contain a listed hazardous waste and must be classified as hazardous only because the pH exceeds 12.5. The State rules and the currently effective federal regulations make a distinction in management requirements based on whether or not the waste is or contains listed hazardous waste. Wastes which contain listed hazardous wastes are subject to more stringent requirements. This distinction is reflective of the difference in risks posed by characteristic hazardous wastes versus listed hazardous wastes. If a waste is hazardous because it exhibits

a characteristic of a hazardous waste in addition to high pH, it is also subject to more stringent requirements. This is reasonable since pH is a characteristic of hazardous waste which can be readily eliminated through neutralization, or potentially, by dewatering. Therefore, if the waste contains no listed waste and does not demonstrate any other characteristic of a hazardous waste (e.g., EP toxicity or ignitability) it presents a minimal hazard to the public and the environment.

In order to qualify for the reduced reuse or recycling requirements, the waste must have been demonstrated not to be a primary irritative substance. Proposed rule Part 7045.0142 establishes the testing procedure which must be used. The reasonableness of the proposed test is discussed below. While the pH of a waste is an indicator of its ability to act as a corrosive or irritative substance, it does not actually test the waste's ability to act as a corrosive. Not all high pH wastes are in fact irritative or corrosive. High pH wastes which are not irritative pose little risk of harm to human health and such wastes may be safely reused or recycled with only minimal management requirements.

Under the proposed amendment, the waste would be subject to the following requirements:

A. Minn. Rules pts. 7045.0214 to 7045.0217. These parts specify the procedures for evaluating the waste and reporting the results to the Agency. It is reasonable to require that the

waste be evaluated since the waste must be tested to assure that it is hazardous only because the pH exceeds 12.5 and that it contains no listed wastes.

B. Minn. Rules pts. 7045.0220 to 7045.0230 and 7045.0240 to 7045.0249. These parts require the generator to submit a hazardous waste disclosure and a management plan for the waste and to obtain a generator identification number. These requirements are reasonable since they provide information regarding the management of the waste and assurance that the management plan is appropriate for the waste being handled.

C. Minn. Rules pt. 7045.0296. This part requires the generator to submit an annual report to the Agency Director. This is a reasonable requirement because hazardous waste manifests are not required and the annual reports will provide information verifying that the waste was in fact reused or recycled and also provide information of the actual volume and destination of the waste.

D. Minn. Rules pts. 7045.1000 to 7045.1030. These parts require compliance with the hazardous waste management ordinances of the seven metropolitan counties. This is reasonable since generators of hazardous waste in the seven metropolitan counties must submit their disclosures to the county rather than to the Agency and to comply with the counties' hazardous waste ordinances.

Proposed rule Minn. Rule pt. 7045.0142 sets forth the testing method to be used to determine whether a high pH waste is a pri-

mary irritative substance. The method required by the rule is the test commonly known as the "rabbit skin patch test." The test is the same one used for evaluation of products by the Consumer Product Safety Commission and was also the testing procedure for determining whether a substance was an irritative substance under the hazardous waste rules adopted by the Agency in 1979. The test procedure was deleted from the rules when the irritative category was deleted in 1984. Use of this testing method is reasonable since it is a standardized procedure used for over forty years.

Proposed Part 7045.0142 provides that an irritative substance is a substance exhibiting skin irritation of an empirical score of five or more as determined by the "rabbit skin patch test." The empirical score of five specified in the proposed rule is that which was used in the Agency's hazardous waste rules as adopted in 1979. The Agency's rationale for adopting the empirical score of five is discussed in the Exhibits and testimony presented during the hearing on the adoption of those rules. Those documents are included as exhibits in this proceeding and are listed in Part VI.

An empirical score of five is also the standard used by the United States Food and Drug Administration (U.S. FDA). It is the opinion of the U.S. FDA that any substance which produces a score of five or more would produce a degree of primary irritation if applied to intact human skin. The categories of irritation

described by the method are erythema, which is redness; edema, raising of the treated skin above the unaffected surrounding skin; and eschars, which are a deeper irritation causing sloughing or scabbing of the outer layer of skin.

For irritation to be moderate to severe, erythema, eschar, and edema formation must reach a value of 2-3. Assuming an average value of 2.5, a score of 5 would result for the 24 hour and 72 hour tests. Scores of less than 5 would indicate the substance would not be classified an irritant to human skin, and does not pose the threat associated with a corrosive substance. Therefore, although the pH of the waste indicates it is a corrosive, this test shows that the waste does not exhibit the ability to act as a corrosive or irritative substance on the skin.

It is reasonable to specify the method to clarify what is meant by an irritative substance. Moreover, as discussed above, it is reasonable to use this particular method since it is standard method used by the United States Consumer Product Safety Commission and has been in use for over 40 years to determine the skin-irritating tendencies of consumer products.

IV. CONSIDERATION OF SMALL BUSINESS

Minn. Stat. § 14.115 (1984) requires Minnesota agencies, when proposing amendments to existing rules which may affect small businesses, to consider reducing the impact of the rule on small businesses. The objective of Minn. Stat. ch. 116 is to protect the public health and welfare and the environment from the adverse

effects which will result when hazardous waste is mismanaged. Considerations which would apply less stringent requirements to the hazardous waste generated by small businesses would be contrary to the MPCA's mandate.

However, the proposed change in reuse or recycle requirements for high pH wastes would subject such wastes to fewer requirements if they were to be reused or recycled. This should promote the reuse and recycling of such wastes and thus reduce the cost of management. The waste generated by small businesses has the same protential for harming human health and the environment as that produced by larger businesses. Moreover, the size of the business does not necessarily relate to the amount or type of waste generated. The impact of improper management of hazardous waste on the environment depends on the waste and not the size of the business which generated the waste. The requirements imposed on the reuse or recycling or high pH wastes by the proposed amendments are the minimum necessary to protect human health and the environment. To the extent that the proposed amendments reduce the cost of hazardous waste management small businesses will benefit.

V. CONCLUSION

The MPCA has, in this document and its exhibits, made its presentation of facts establishing the need for and reasonableness of the proposed amendments to Minnesota's hazardous waste rules. This document constitutes the MPCA's Statement of Need and

Reasonableness for the proposed amendments to the hazardous waste rules.

VI. LIST OF EXHIBITS

The Agency is relying on the following documents to support these amendments.

MPCA Ex. No.	Title
1	16 Code of Federal Regulations, section 1500.41. Method of testing primary irritant substances.
2	Toxicological Criteria for Defining Hazardous Wastes, Pacific Northwest Laboratories, Batelle Memorial Institute, September 30, 1976
3	In the Matter of the Proposed Adoption of Rules Governing the Identification, Classification, Storage, Collection, Transportation and Disposal of Hazardous Waste and of Amendments to the Minnesota Regulations SW 1, 2, 3, 4, 6 and 7. Transcript of Hearing, Vol. II, October 24, 1977, pages 193 - 195; Vol. III, October 25, 1977, pages 229 - 235, 299, 300, 314, 315, and 364
4	Primary Dermal Irritation Test on Lime Sludge, Raltech Laboratories, Madison, Wisconsin, September 1981.

Dated: March , 1985

THOMAS J. KALITOWSKI
EXECUTIVE DIRECTOR

16 CFR 1500.41 (1984)

EXHIBIT 1

(b) *Preparation of test animal.* The animals are prepared by clipping the skin of the trunk free of hair. Approximately one-half of the animals are further prepared by making epidermal abrasions every 2 or 3 centimeters longitudinally over the area of exposure. The abrasions are sufficiently deep to penetrate the stratum corneum (horny layer of the epidermis) but not to distrub the derma; that is, not to obtain bleeding.

(c) *Procedures for testing.* The sleeve is slipped onto the animal which is then placed in a comfortable but immobilized position in a multiple animal holder. Selected doses of liquids and solutions are introduced under the sleeve. If there is slight leakage from the sleeve, which may occur during the first few hours of exposure, it is collected and reapplied. Dosage levels are adjusted in subsequent exposures (if necessary) to enable a calculation of a dose that would be fatal to 50 percent of the animals. This can be determined from mortality ratios obtained at various doses employed. At the end of 24 hours the sleeves or screens are removed, the volume of unabsorbed material (if any) is measured, and the skin reactions are noted. The subjects are cleaned by thorough wiping, observed for gross symptoms of poisoning, and then observed for 2 weeks.

§ 1500.41 Method of testing primary irritant substances.

Primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in abraded and intact skin tests. Introduce under a square patch, such as surgical gauze measuring 1 inch by 1 inch and two single layers thick, 0.5 milliliter (in the case of liquids) or 0.5 gram (in the case of solids and semisolids) of the test substance. Dissolve solids in an appropriate solvent and apply the solution as for liquids. The animals are immobilized with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with an impervious material, such as rubberized cloth, for the 24-hour period of exposure. This material aids in maintaining the test patches in position and retards the evaporation of volatile substances. After 24 hours of exposure, the patches are removed and the resulting reactions are evaluated on the basis of the designated values in the following table:

Skin reaction	Value[1]
Erythema and eschar formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formations (injuries in depth)	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

[1]The "value" recorded for each reading is the average value of the six or more animals subject to the test.

Readings are again made at the end of a total of 72 hours (48 hours after the first reading). An equal number of exposures are made on areas of skin that have been previously abraded. The abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or to produce bleeding. Evaluate the reactions of the abraded skin at 24 hours and 72 hours, as described in this paragraph. Add the values for erythema and eschar formation at 24 hours and at 72 hours for intact skin to the values on abraded skin at 24 hours and at 72 hours (four values). Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score; for example:

Skin reaction	Exposure time (hours)	Evaluation value
Erythema and eschar formation:		
Intact skin	24	2
Do	72	1
Abraded skin	24	3
Do	72	2
Subtotal		8

Skin reaction	Exposure time (hours)	Evaluation value
Edema formation:		
Intact skin	24	0
Do	72	1
Abraded skin	24	1
Do	72	2
Subtotal		4
Total		12

Thus, the primary irritation score is $12 \div 4 = 3$.

§ 1500.42 Test for eye irritants.

(a)(1) Six albino rabbits are used for each test substance. Animal facilities for such procedures shall be so designed and maintained as to exclude sawdust, wood chips, or other extraneous materials that might produce eye irritation. Both eyes of each animal in the test group shall be examined before testing, and only those animals without eye defects or irritation shall be used. The animal is held firmly but gently until quiet. The test material is placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test substance is dropped. The lids are then gently held together for one second and the animal is released. The other eye, remaining untreated, serves as a control. For testing liquids, 0.1 milliliter is used. For solids or pastes, 100 milligrams of the test substance is used, except that for substances in flake, granule, powder, or other particulate form the amount that has a volume of 0.1 milliliter (after compacting as much as possible without crushing or altering the individual particles, such as by tapping the measuring container) shall be used whenever this volume weighs less than 100 milligrams. In such a case, the weight of the 0.1 milliliter test dose should be recorded. The eyes are not washed following instillation of test material except as noted below.

(2) The eyes are examined and the grade of ocular reaction is recorded at 24, 48, and 72 hours. Reading of reactions is facilitated by use of a binocular loupe, hand slit-lamp, or other expert means. After the recording of observations at 24 hours, any or all eyes may be further examined after applying fluorescein. For this optional test, one drop of fluorescein sodium ophthalmic solution U.S.P. or equivalent is dropped directly on the cornea. After flushing out the excess fluorescein with sodium chloride solution U.S.P. or equivalent, injured areas of the cornea appear yellow; this is best visualized in a darkened room under ultraviolet illumination. Any or all eyes may be washed with sodium chloride solution U.S.P. or equivalent after the 24-hour reading.

(b)(1) An animal shall be considered as exhibiting a positive reaction if the test substance produces at any of the readings ulceration of the cornea (other than a fine stippling), or opacity of the cornea (other than a slight dulling of the normal luster), or inflammation of the iris (other than a slight deepening of the folds (or rugae) or a slight circumcorneal injection of the blood vessels), or if such substance produces in the conjunctivae (excluding the cornea and iris) an obvious swelling with partial eversion of the lids or a diffuse crimson-red with individual vessels not easily discernible.

(2) The test shall be considered positive if four or more of the animals in the test group exhibit a positive reaction. If only one animal exhibits a positive reaction, the test shall be regarded as negative. If two or three animals a positive reaction, the test is repeated using a different group of six animals. The second test shall be considered positive if three or more of the animals exhibit a positive reaction. If only one or two animals in the second test exhibit a positive reaction, the test shall be repeated with a different group of six animals. Should a third test be needed, the substance will be regarded as an irritant if any animal exhibits a positive response.

(c) To assist testing laboratories and other interested persons in interpreting the results obtained when a substance is tested in accordance with the method described in paragraph (a) of this section, an "Illustrated Guide for Grading Eye Irritation by Hazardous Substances" will be sold by the Superintendent of Documents, U.S. Government Printing Office, Washington,

Chapter II—(

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[38 FR 27012, Nov. 1, 1973]

§ 1500.43 Meth volatile fla blue open-c

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PCA EXHIBIT 2
Exhibit 26

PCA DEP. EX. 26
DATE 1/30/79 B.JW. 6QW

Toxicological Criteria for Defining Hazardous Wastes

September 30, 1976

Developed for

Minnesota Pollution Control Agency
1935 County Road, B-2
Roseville, Minnesota 55113

Battelle
Pacific Northwest Laboratories

Control Act Amendments of 1972, not a single material was selected on that basis.[6] Thus, materials which may qualify as phytotoxic also demonstrate sufficient aquatic or mammalian toxicity to be designated by other criteria. Should a good standard phytotoxic evaluation be developed in the future, use of related criteria could be reconsidered.

Corrosive/Irritation

Acidity and alkalinity are not the sole material properties which may cause corrosion or irritation of skin as a result of direct contact. Consequently, it is necessary to consider additional criteria for materials which may irritate or damage skin upon contact. The obvious concern here is for operators or handlers, who may come into contact with a waste during the management cycle as well as for the general public which could come in direct contact with wastes at landfills or other sites open to public access.

The mode of action is straight forward. Similarly, the degree of effect is relatively easy to specify. Wastes should be designated as hazardous if they are corrosive or cause severe irritation. Corrosive materials are those that cause irreversable damage to tissue as observed after application to skin. Standard tests are described by Hagen and Draize and the National Academy of Sciences (Appendix C). Primary irritation requires a more subjective judgement.

Basically, severe irritation is evidenced by erythema and eschar formation, and/or edema formation. Erythema is a redness of the skin while eschar formations care associated with a similar injury in depth. Edema refers to raising of the skin above the unaffected surrounding skin. The appropriate test and a scoring system for results are described in 16 CFR 1500.41 which is reprinted below:

1500.51 Method of testing primary irritant substances.

Primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in abraded and intact skin tests. Introduced under a square patch, such as surgical gauze measuring 1 inch by 1 inch and two single layers thick, 0.5 mililiter (in the case of liquids) or 0.5 gram (in the case of solids and semi-solids) of the test substance. Dissolve solids in an appropriate solvent and apply the solution as for liquids. The animals are immobilized with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with an impervious material, such as rubberized cloth, for the 24-hour period of exposure. This material aids in position and retards the evaporation of volatile substances.

exposure, the patches are removed and the resulting reactions are evaluated on the basis of the designated values in the following table:

Skin Reaction	Value[1]
Erythema and eschar formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formations (injuries in depth)	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

[1]The "value" recorded for each reading is the average value of the six or more animals subject to the test.

Readings are again made at the end of the total of 72 hours (48 hours after the first reading). An equal number of exposures are made on areas of skin that have been previously abraded. The

abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or to produce bleeding. Evaluate the reactions of the abraded skin at 24 hours and 72 hours, as described in this paragraph. Add the values for erythema and eschar formation at 24 hours and at 72 hours (four values). Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score; for example:

Skin Reaction	Exposure Time (Hours)	Evaluation Value
Erythema and eschar formation:		
Intact Skin	24	2
Do	72	1
Abraded Skin	24	3
Do	72	2
Subtotal		8
Edema formation:		
Intact Skin	24	0
Do	72	1
Abraded skin	24	1
Do	72	2
Subtotal		4
TOTAL		12

Thus, the primary irritation score is 12 ÷ 4 = 3.

For irritation to be moderate to severe, erythema, eschar and edema formation must reach a value of 2-3. Assuming an average of 2.5, this would correspond with a total primary irritation score of 5. Therefore, hazardous wastes are defined as those which show corrosive (irreversible) effects on skin or yield a primary irritation score of 5. Further information on irritation testing can be found in the appended papers by Hagen and Draize, and the National Academy of Sciences (Appendix C).

Recommended Criteria

In summary, it is posited that the most equitable approach to designating wastes as hazardous or nonhazardous is based on the selection of quantitative criteria where possible and that these criteria should reflect the nature of waste management activities. In particular, a technical rationale should be employed to select criteria as opposed to reliance on designations generated for other types of materials under other circumstances. This approach has been applied for the development of a working definition of hazardous wastes for utilization in MPCA regulatory program. Based on the potential hazard exposure modes discussed in preceeding sections, the following criteria are recommended for that program:

- Oral Toxicity - $LD_{50} \leq 500$ mg/Kg body weight;
- Dermal Toxicity - $LD_{50} \leq 1000$ mg/Kg body weight;

Reprinted from:

Draize, J. H. 1965. Appraisal of the safety of chemicals in foods, drugs, and cosmetics - Dermal toxicity. Assoc. of Food and Drug Officials of the U.S. Topeka, Kansas. Pp. 46-59.

DERMAL TOXICITY

J. H. Draize, Ph.D., Chief, Skin Toxicity Branch

This revision of the section on dermal toxicity varies from the 1955 edition by the addition of sections on photosensitization and aerosol preparations. There are a number of minor revisions in detail on the sections on local and systemic dermal toxicity procedures.

Any substance capable of eliciting a reaction when applied topically to the skin, its appendages, or to mucous membrane demonstrates a capacity for absorption. On absorption by the skin or mucous membranes, substances may elicit local effects (local toxicity) or systemic effects (systemic toxicity) or both. The local effects are more properly termed "irritations," a general term to describe essentially eczematous or contact dermatoses in the case of the skin or of inflammation in the case of mucous membranes. Skin irritation may result from contact with substances which are primary irritants or from contact with substances producing sensitizations. A third type of local skin effect is recognized, and is termed "skin fatigue."

SOLVENTS OR VEHICLES FOR AGENTS IN DERMAL STUDIES

Whenever possible a formulation intended for topical use should be studied as submitted. Frequently it is desirable to determine the toxicity of one or more of the individual components of a formulation. The choice of a proper solvent or vehicle in such studies often poses a problem. The solvent or vehicle must permit solution, or at least a colloidal dispersion (for example, emulsion or fine suspension). However, the solvent of choice must not *per se* disturb significantly the normal physiological function of the skin nor contribute to the over-all toxicity of the compound under study. Although the solubility characteristics of the many varied agents which may come under study does not permit an enumeration of such solvents or vehicles, dimethyl phthalate, or aqueous solutions of ethyl alcohol, or isopropyl alcohol, or propylene glycol have been found suitable for a wide variety of substances.

LOCAL TOXICITY

(a) Primary Irritation of the Skin. If the skin tissue is able to deal with the excitant (irritating substance), the reaction is physiological (normal); however, if the action of the excitant is excessive, the reaction is pathological (abnormal), and irritation results. Irritation is an extreme reaction of tissues to an insult, or injury and is best characterized as incipient inflammation. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and resiculation, and finally to an intense suppurative process. Irritation *per se* is not measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

A primary irritant may be defined as a substance producing an injury on first contact. The resultant injury will depend on:

(1) Nature of irritant

(2) Concentration of irritant

(2) Total elapsed time of exposure

Primary irritation of the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit clipped free of hair. A minimum of six subjects is used per preparation tested. The method consists of introducing under a one-inch patch 0.5 ml. (in case of liquids) or 0.5 gm. (in case of solids and semisolids) of the test substance. It is also desirable in the case of solids to attempt solubilizing in an appropriate solvent (see above) and to apply the solution as for liquids. The animals are immobilized in an animal holder with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with rubberized cloth for the entire 24-hour period of exposure. This latter procedure aids in maintaining the test patches in position, and, in addition, retards the evaporation of volatile substances. After the 24 hours of exposure the patches are removed, and the resulting reactions are evaluated on the basis of scores in Table 1.

Readings are made also after 72 hours, and the final score represents an average of the 24- and 72-hour readings. An equal number of exposures are made on areas of skin which have been previously abraded. The abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma (that is, not sufficiently deep to produce bleeding).

TABLE 1

Evaluation of Skin Reactions

(1) Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score	4
(2) Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score	4

The total erythema and edema scores are added in both the 24- and 72-hour readings, and the averages of the scores for intact and abraded skin are combined; this combined average is referred to as the primary irritation index. It is useful for placing compounds in general groups with reference to irritant properties.

Compounds producing combined averages (primary irritation indexes) of 2 or less are only mildly irritating; whereas those with indexes from 2 to 5 are moderate irritants, and those with scores above 6 are considered severe irritants.

(b) Testing of Rubefacients or Counterirritants. The testing of rubefacients and counterirritants presents a special problem. These substances are formulated to produce some degree of local skin irritation. However, a counterirritant must not, through its prescribed use, elicit frank skin damage, namely, necrosis or eschar formation. In the testing of such preparations, the recommended procedure is to apply the formulation to the clipped skin of the back and flanks of the albino rabbit according to the label directions for the product. Consideration is given to the total skin area treated and the reactions produced. The mechanical details of this experiment are similar to those described in the 20-day subacute dermal toxicity procedures described in a subsequent item of this section, except that dosages are not related to the body weight of the experimental subject. A minimum of six albino rabbits (three with intact and three with abraded skin) is employed.

STATE OF MINNESOTA

MINNESOTA POLLUTION CONTROL AGENCY

In the Matter of the Proposed Adoption of Rules Governing the Identification, Labeling, Classification, Storage, Collection, Transportation and Disposal of Hazardous Waste and of Amendments to the Minnesota Regulations SW 1, 2, 3, 4, 6 and 7.

VOLUME II

File No. PCA-78-003-W

The above entitled matter came duly on before William Seltzer, Hearing Examiner, on the 24th day of October, 1977, in the Hearing Room of the Offices of the Minnesota Pollution Control Agency, 1935 West County Road B2, Roseville, Minnesota, commencing at approximately 9:30 o'clock a.m.

* * *

Section HW3BC --

Q Excuse me, Mr. Kinsey. I think there might be a typo in there. You are going to refer to the irritative material as in your typed testimony, that's really an HW2B3C, is that correct?

A Yes, it is.

Section HW2B3C provides that a waste which is an irritative material be classified as a hazardoud waste.

HW1B19 defines an irritative material as a non-corrosive material which has the property to cause local reversible injury to a biological membrane at the site of contact and is determined by: A. The practical experience with the waste where the long-term exposures have causedfirst degree burns and where the long-term exposures have caused -- the short-term exposures have caused first degree burns and where longer exposures have caused second degree burns; or B. The skin irritation of an empirical score of 5 or more as pursuant to title 16 of the CFR section 1,500.41, the primary skin irritation procedure is the one used by the consumer product safety commission.

The eye irritation criteria of the consumer product

safety commission were not used because of concern that the irritative nature of many wastes that are suitable for routine waste management may be due to pieces of grit and dirt and in the test sample that would result in their inappropriate classification as hazardous wastes. The experience criteria was added as an economical alternative to biological testing that was referred to in 16CFR and to be used in cases where the generator has practical experience in handling the waste.

The Department of Transportation's definition of an irritative material takes into account not only those materials which give off intensive irritating fumes, but also those that when you contact the fire would give off intensively irritating fumes. Their definition does not refer to a particular task, but rather gives the examples such as bromobenzocyanide and chlorosetaphnyl and diaphenylmunochlorinoxyn and diaphynlchlorinoxine.

The Department of Transportation's definition is not the same as ours, nor is the consumer product safety commission's definition, but it's not incompatible with either one. But our definition isn't compatible with either one of them.

Because the Department of Transportation does not specify tests by which a material is determined to be hazardous or not hazardous the two definitions have

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considerable overlap. Therefore, the definition that we have may or may not be more strict than the Department of Transportation, it is certainly more precise and it is easier to determine whether a material might be irritative under our definition as it is then under the Department of Transportation's.

MR. SELTZER: Let's go off the record for a second.

(At this time a discussion was had off the record)

MR. SELTZER: Let's take a short recess. Either that or we can adjourn now at 4:30 and then pick up tomorrow morning.

MR. EARLY: That might be a good idea because he has, you know, a considerable ways to go probably in just completing this line and after recess it might get to get rather late.

MR. SELTZER: Okay. The witness did look like he was getting uncomfortable. Yes, sir.

MR. BALSIZER: I am Gary Balsizer with the Union Oil Company. I am wondering if we could ask some questions pertaining to what's been said so far?

MR. SELTZER: Well from seeing what's ahead I don't know that this is a logical break point because the witness is now covering those areas that they are classifying as hazardous, but I will certainly defer to counsel.

jah

STATE OF MINNESOTA

MINNESOTA POLLUTION CONTROL AGENCY

In the Matter of the Proposed Adoption of Rules Governing the Identification, Labeling, Classification, Storage, Collection, Transportation and Disposal of Hazardous Waste and of Amendments to Minnesota Regulations SW 1, 2, 3, 4, 6 and 7.	File No. PCA-78-003-WS

VOLUME III

* * *

The above-entitled matter came duly on before William Seltzer, Hearing Examiner, on the 25th day of October, 1977, in Room 83 of the State Office Building, St. Paul, Minnesota, commencing at approximately 9:30 o'clock a.m.

* * *

MR. SELTZER: Let's go back on the record.

Mr. Early, will you please continue with your Examination of the witness.

Q (by Mr. Early continuing) Mr. Kinsey, then, would you continue to read from your prepared statement spot where you left off yesterday which I understand - correct me if I'm wrong - is the middle of Page 21?

A Yes, that's correct. Section HW 2 B 3 d provides that a waste which is a corrosive material be classified as a hazardous waste.

MR. SELTZER: Let me interrupt the witness here. What section are you referring to?

THE WITNESS: HW 2 B 3 d.

Q Okay. Maybe we should note that you are on Page 527, it's on the right-hand side of the page --

A It's on the left-hand side of the page.

Q I'm sorry, left-hand side, three quarters of the way down or so.

A It says, "d. A corrosive material." The definition of a corrosive material is closely related to that of an irritative material and in HW 1 B 5 a corrosive material is defined as one having anyone of three different properties, a pH that is greater than 12 or less than 3, the ability to cause a visual destruction or irreversible alteration of skin tissues at the site of contact when tested by the same technique as for an irritative material, or third, it's a corrosive material if it has a corrosion rate greater than 0.25 inches per year or more when tested on the Society of Automotive Engineers steel, 1020, according to the requirements in the National Association of Corrosion Engineers Standard TM-01-69. Again as with the irritative materials, the definition of corrosive materials is closely related to the Department of Transportation's definition and the Consumer Product Safety Commission's definition. The Department of Transportation being found in 49 CFR, Section 173 and the Consumer Products Safety definition being found in 16 CFR, Sections 1500.

MR. EARLY: Excuse me. Mr. Hearing Examiner, we ask that you take administrative notice of those sections of the Code of Federal Regulations.

MR. SELTZER: I will so take administrative notice, Counsel.

A The Department of Transportation defines a corrosive

material as a material that causes irreversible alteration in human skin when tested in accordance with the Consumer Product Safety Commission's rabbit skin test and it is to be tested for a period of four hours or less. The Department of Transportation defines a corrosive material - it goes beyond - the Department of Transportation goes beyond the biological test in defining a corrosive material, and it also includes a criteria that if it shows a corrosion rate on either aluminum or steel in excess of a quarter of an inch per year, that it be a corrosive material, and also gives a provision in there that provides for human experience. In other words, if there is an indication that the material is either greater or less hazardous than that indicated by either one of those tests, then that experience could be used in classifying that material for transportation.

The Consumer Product Safety Commission, on the other hand, uses only the rabbit skin test which is a biological test and it determines the irreversibility of damage to the skin. It's also, as I said before, the same test that's used in irritation and what it becomes, essentially, is depending upon what happens to the rabbit skin. If not much happens as defined by a particular scale, it's irritative, but if it goes so far as to cause an irreversible damage to the rabbit's skin, it becomes corrosive. So the procedure is the same, it's just the results that you get

at the end of the test that make it different.

We selected a pH --

Q Excuse me, Mr. Kinsey. You noted DOT defines a corrosive material as one that has a corrosion rate on either aluminum or steel, and in the proposed regulations you have a corrosion rate only on steel. Could you explain briefly why aluminum is not included?

A The DOT included aluminum because a number of years ago there were aluminum tankers that were used to transport hazardous materials. But that has largely been eliminated and has gone out of service, and DOT plans on eliminating, reducing that particular requirement. We eliminated it now because we know of no instances where aluminum to contain the waste for disposal. Aluminum is too valuable as a resource for recovery, as a recoverable metal. Therefore, to require everybody to do a test to determine if a material is corrosive to aluminum would have no real applicability to the disposal of that waste. So we did not require it.

We did select a pH criteria also. The pH that is greater than 12 or less than 3. The pH is a measure of the acidity and the basisity or the alkalinity of a particular solution. In other words, if something is acid, it has a very low pH. If something is alkaline, like lye for instance, a solution of, like Draino and such would have a very high pH. And it has to do with a number of -

I guess there's no reason to get into the explanation of that any further. We selected this criteria, first of all --

Q Excuse me, Mr. Kinsey. Maybe you could explain the significance of the pH number.

A I will do that.

Q Okay.

A Okay. The solutions that have a pH that is either greater than 12 or less than 3 could generally be - they would cause an irreversible alteration of skin tissues, and if you were to run the test on them, the mere fact that that high a pH or that low a pH is corrosive to the skin means that it would be kind of wasteful to do a test that would cost maybe a couple hundred dollars when you could take a pH paper which would cost only a few cents and know without actually splashing the stuff on you that that stuff is really going to be corrosive and it's going to cause an irreversible damage to the rabbit's skin.

A pH less than 3 also has the - being on the acidic side, these types of wastes would be dangerous in a sanitary landfill situation because they would tend to further lower the pH of the leachate within the landfill of the material of the water as it goes through the landfill, and that would tend to solubilize the heavy metals that are in there and make the problem at that landfill that much worse.

Q Excuse me, Mr. Kinsey. By that, could you just explain a

little bit what you mean by problem worse in solubilizing the heavy metals?

A The heavy metals ions in a sanitary landfill situation will stay in place as long as they don't become soluble, and move with the water and thereby leave the landfill in a leachate. And if you have an acidic situation with a very low pH, then you will tend to increase the amount of metal which is solubilized and therefore leaves the landfill and is no longer contained in the landfill.

Q Is it then the desirable thing from the pollution standpoint to contain as many of these heavy metals in the landfill as you can?

A Yes, it is.

Q Thank you.

A A pH of greater than 12 and less than 3 also provides a hazard in the sanitary landfill situation where the leachate generated with this pH would be discharged into a stream or lake that could be located as close as a half a mile from the site because at that level it would kill aquatic life if that leachate, if that material were subsequently discharged.

Q Excuse me, Mr. Kinsey. Could you explain what you are getting at there? I think maybe it didn't come through very clearly.

A It's another reason for requiring a pH at those particular levels, not so much because it's corrosive, but because it

has toxic effects, and if you dispose it, a waste, with those pH's into a sanitary landfill situation, it is totally conceivable that that waste will result in a leachate which will kill fish or aquatic life that are located in the waters where that leachate discharges into.

Q That would be because the leachate, itself, would have a high pH?

A That's because the leachate, itself, would have a high pH. The ability to cause a visible destruction or irreversible alteration at the site of contact is the portion of the definition common to both the Department of Transportation and the Consumer Product Safety Commission. The comustion rate which is part of the Department of Transportation's definition is important also to include both in order that it be compatible with DOT and this is because wastes are often contained within steel containers and vehicles. As mentioned before, we did drop the aluminum requirement that DOT has because we were not aware of any instances where aluminum was used to contain waste. Therefore there didn't seem to be any reason to include it.

We next considered a parameter of acidity or basicity from a corrosive standpoint. We concerned ourselves here with three possible scenarios, the first being direct contact. It has been determined that primary irritation can be obtained from a substance which evidences a pH of less than 2.5 or greater than 11.5. It should be noted, however, that those levels are determined with tests on corneal membranes, that is, contact with the eye as opposed to contact with the epidermis or the outside skin.

The second scenario we considered was the potential for pH contamination of ground water subsequently used for domestic or recreational purposes. Once again we considered an effective dilution of 100 to 1. The National Academy of Sciences has recommended that water used for domestic use or bathing purposes not have a pH value of less than five or greater than nine. If we institute the effected dilution factor of 100, this would suggest that a material would be hazardous if in its present form prior to leaching into the ground water it has a pH of less than three or greater than 11.

The third scenario considered was the possibility that acid or base properties of a hazardous waste could evidence

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effects on aquatic communities exposed via contamination of a aquifer which subsequently fed surface waters. It was necessary at this point to extend the scenario, in that we are still using an effective dilution of 100 to 1 for movement of the leachate from the landfill area to the ground water aquifer. However, the ground water, as it enters the surface water, will once again be diluted and credit for that dilution should be made.

There are a wide range of scenarios suggested here. There are springs and freshets which receive this entire supply from ground water aquifers, and therefore would evidence no dilution upon entering of the leachate. However, it is more often the case that ground water at any one point in the surface water will constitute less than one percent of the total flow in that water volume. We chose to select this more conservative estimate and thereby credit the surface water of an additional dilution of 100 to 1. So that from movement from the landfill to the surface water which would sustain a viable aquatic community, the leachate itself will be diluted by a factor of 10,000. Once again, the National Academy of Sciences has suggested that viable aquatic communities cannot be maintained if the pH level falls below 6.5 or greater than 8.5. Instituting the 10,000 to 1 dilution factor, this would suggest that a material would be a hazardous waste if it has a pH value of less than

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2.5 or greater than 12.5.

In considering these scenarios, we chose to define the criteria for hazardous waste those materials having a pH value of less than 3 or greater than 12. This compares to values from other states in the following manner: The State of Washington has defined as hazardous wastes with a pH of less than 3 or greater than 11 when a waste is diluted with an equal weight of water, California has defined as hazardous waste wastes that have a pH of less than 2 or greater than 12. The current draft of the proposed EPA criteria for defining hazardous wastes on a national basis is a pH value of less than 2 or greater than 12. Therefore, we are in full compliance on the upper end, suggesting the pH greater than 12. We agree with one of the three in using a value of less than 3. The other two have chosen to use the slightly lower value of a pH less than 2.

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We finally looked at one last parameter, corrosive irritation. Specifically, we were concerned with the ability of a waste when in direct contact with an operator or other individuals to provide irreversible effect or primary irritation. We therefore recommend that waste be defined as hazardous if they are capable of producing either of these effects, that is irreversible effects to the skin or moderate or severe primary irritation. We would define the latter as the development of moderate or severe eryethema, which is a redness of the skin or a chemical burn, if you will; eschar, which is the same affect in depth in the skin or edema, which is a raising or production of a welt on the skin from contact with the waste. These effects can be quantified utilizing a standard primary irritation test as recommended by the National Academy of Sciences and published in 16 CFR 1500.41. We would recommend that utilization of this test with results of 5 or greater on the primary irritation scale would constitute a waste that is hazardous.

In any other taking of this type, it is impossible to select scenarios which will satisfy all interests. There is certainly a degree of subjectivity involved in the

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selection of the scenarios and in interpretation of the results. Therefore, we feel that a third judgment should be passed upon criteria. This is a judgment of reasonability. We therefore took our criteria or the criteria we recommended as a result of our work and applied them to numerous chemical mateials and waste materials to determine which of these would indeed have qualified as hazardous waste and which would not.

In applying the criteria to the 109 toxic pollutants presently receiving affluent limitations as a result of Section 307 of the Water Pollution Control Act Amendments and the consent agreed between the NRDC and the EPA, we found that all 109 toxic pollutants, if taken as a pure material, would meet the criteria as a hazardous waste if they were disposed of in that state. Secondly, we reviewed documented cases reported by the Environmental Protection Agency of damage resulting from improper management of wastes. In all cases we found that those wastes which, in fact, produced damage to the environment or to human health, would have qualified as hazardous wastes under the recommended criteria.

We were also concerned that any criteria requiring testing of the wastes could impose an economic burden on the generators. If one were to do a full battery of toxicological testing on a waste material, the bill could exceed

A Next consider the evaluation of corrosive potential wastes. Since skin damage is a very likely harmful effect of exposure to wastes, a test for determining the corrosive properties of a waste is proposed as appears in the State Register HW 1 B 5. This test has been adopted from well established regulations employed by the Department of Transportation and by the consumer products safety commission for many years and their adoption here is reasonable. It should be pointed out that this test uses a subjective end-point; namely, redness, or erythema and swelling, but one that is because of extensive experience well characterized and appropriate for waste management.

Q Dr. Anders, would a substance with a PA of 12 damage the skin?

A Yes, unless immediately washed off it would damage the skin.

Q What about substance with a PH of 3?

A By the same token, unless removed from the skin it would damage the skin.

Q Thank you.

MA.

EXHIBIT 4

and engineering laboratory, inc.
662 CROMWELL AVENUE
ST. PAUL, MN 55114
PHONE 612-645-3601

November 4, 1981

C S McCrossan, Inc
Box AD
Osseo, MN 55369

Attention: Ray Hite

Dear Mr Hite

Enclosed are copies of the dermal irritation test results on the two samples of lime sludge.

These samples were taken on Septmeber 17, 1981 in coordination with Lisa Thorvig of the MPCA and personnel of C S McCrossan. Sample #1 (our laboratory #3027) is a cross-section of undisturbed material taken in the pit. Sample #2 (our laboratory #3028) is a sample of wetter material taken from the scoop of a crane which was transferring the lime to higher ground. According to the results, sample #2 is more irritative than #1, but still not enough so to fail the test. It can be seen that neither sample is irritative or corrosive.

The method employed in this testing was the FHSA Method for Dermal Irritation. The FHSA Method is the test described in 16 CFR § 1500.41 (1977), and referred to by 6 MCAR § 4.9001 B.5 (page 3 of the Minnesota Pollution Control Agency Hazardous Waste Rules).

If you have any questions, please feel free to contact me at 645-3601, ext 125.

Sincerely

Richard J Hlavka

Richard J Hlavka
Environmental Specialist

RJH/ms

Encl.

Raltech
SCIENTIFIC SERVICES
P.O. Box 7545 • Madison, Wisconsin 53707 • 608/241-4471
A Division of Ralston Purina Company

REPORT

RICHARD J. HLAVKA
TWIN CITY TESTING
662 CROMWELL AVENUE
ST. PAUL, MN 55114

RT LAB NO. 896899
ENTERED 09/23/81
REPORTED 10/15/81

LIME SLUDGE: LAB #3027; SAMPLE #1

PURCHASE ORDER NUMBER C 3442

ENCLOSED:

PRIMARY DERMAL IRRITATION - METHOD, SUMMARY

RAW DATA ATTACHED

SIGNED: Gary W. Thompson
GARY W. THOMPSON, BS
MANAGER, ACUTE TOXICOLOGY

BY AND FOR RALTECH SCIENTIFIC SERVICES, INC.

Raltech
SCIENTIFIC SERVICES
P.O. Box 7545 • Madison, Wisconsin 53707 • 608 241 4471
A Division of Ralston Purina Company

LIME SLUDGE: LAB #3027; SAMPLE #1

PRIM SKIN IRRITATION

TEST ANIMAL: YOUNG ADULT RABBITS (APPROXIMATELY 14 WEEKS OF AGE) OF THE NEW ZEALAND WHITE STRAIN WERE MAINTAINED INDIVIDUALLY IN SCREEN BOTTOM CAGES IN TEMPERATURE AND HUMIDITY CONTROLLED QUARTERS, PROVIDED CONTINUOUS ACCESS TO COMMERCIAL LABORATORY FEED AND WATER, AND HELD FOR AN ACCLIMATION PERIOD OF AT LEAST 7 DAYS.

THREE MALE AND THREE FEMALE ACCLIMATED ANIMALS WERE CHOSEN AT RANDOM FOR THE TEST, TREATED, AND MAINTAINED DURING THE OBSERVATION PERIOD AS SPECIFIED FOR THE ACCLIMATION PERIOD. TEST ANIMALS WERE IDENTIFIED BY ANIMAL NUMBER AND CORRESPONDING EAR TAG. TWENTY-FOUR HOURS BEFORE TREATMENT THE HAIR WAS CLIPPED FROM THE BACK AND FLANKS OF EACH ANIMAL.

PREPARATION AND CONCENTRATION OF TEST MATERIAL: AS SUBMITTED, PH DETERMINED TO BE APPROXIMATELY 12.5

TREATMENT: JUST BEFORE THE TEST MATERIAL WAS APPLIED, CRISSCROSS EPIDERMAL ABRASIONS WERE MADE ON ONE EXPOSED AREA OF EACH RABBIT TO PROVIDE ONE ABRADED AND ONE INTACT TEST SITE. (THE ABRASIONS WERE SUFFICIENTLY DEEP TO PENETRATE THE STRATUM CORNEUM, BUT NOT DEEP ENOUGH TO PENETRATE TO THE DERMAL LAYER AND CAUSE BLEEDING.)

THE TEST MATERIAL WAS APPLIED TO THE TWO TEST SITES ON EACH RABBIT IN THE AMOUNT OF 0.5 ML PER SITE. EACH TREATED AREA WAS COVERED WITH A 5.0 X 5.0 CM GAUZE PATCH SECURED WITH PAPER TAPE AND OVERWRAPPED WITH SARAN WRAP AND ELASTOPLAST TAPE TO MAINTAIN THE TEST MATERIAL IN CONTACT WITH THE SKIN AND DECREASE THE RATE OF EVAPORATION. COLLARS WERE APPLIED TO THE ANIMALS FOR THE 24-HOUR TREATMENT PERIOD.

OBSERVATIONS: AFTER TREATMENT THE PATCHES WERE REMOVED AND THE TEST MATERIAL WAS WIPED (NOT WASHED) FROM THE AREA AS THOROUGHLY AS POSSIBLE WITHOUT IRRITATING THE SKIN. THE DEGREE OF ERYTHEMA AND EDEMA WAS READ ACCORDING TO THE DRAIZE TECHNIQUE.* A SECOND READING WAS TAKEN AT 72 HOURS TO DETERMINE THE PRIMARY IRRITATION INDEX FOR THE SAMPLE.

PATHOLOGY: AT STUDY TERMINATION ALL ANIMALS WERE EUTHANATIZED AND DISCARDED.

*DRAIZE, J. H., 1959, APPRAISAL OF THE SAFETY OF CHEMICALS IN FOODS, DRUGS AND COSMETICS - DERMAL TOXICITY. ASSOCIATION OF FOOD AND DRUG OFFICIALS OF THE U.S., TOPEKA, KANSAS, PP. 49-51.

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T LAB NUMBER 896899 PAGE 3

TME SLUDGE: LAB #3027; SAMPLE #1

RIM SKIN IRRITATION(CONTINUED)
TEST ANIMAL: NEW ZEALAND WHITE STRAIN RABBITS
SOURCE: KUIPER'S RABBITRY, GARY, IN
DATE ANIMALS RECEIVED: 9/16/81
DATE TEST STARTED: 9/28/81 DATE TEST COMPLETED: 10/1/81

PRIMARY DERMAL IRRITATION SCORE	6 RABBIT MEAN
24 HOURS:	1.3
72 HOURS:	1.4

PRIMARY DERMAL IRRITATION INDEX:* 1.4

*THE PRIMARY DERMAL IRRITATION INDEX IS THE SUM OF THE 24 AND 72-HOUR PRIMARY DERMAL IRRITATION SCORES, DIVIDED BY TWO AND ROUNDED TO THE NEAREST TENTH.

CONCLUSION:
ACCORDING TO FHSA REGULATIONS, THIS COMPOUND IS NOT A PRIMARY SKIN IRRITANT.

ATTACHMENT I

SCALE FOR SCORING SKIN REACTIONS

Erythema and Eschar Formation:	Value
No erythema	0
Doubtful or barely perceptible	0.5
Very slight erythema	1
Slight, not well defined	1.5
Well defined erythema	2
Moderate	2.5
Moderate to severe erythema	3
Severe, not beet red	3.5
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Edema Formation:	
No edema	0
Doubtful or barely perceptible	0.5
Very slight edema	1
Slight, not well defined	1.5
Slight edema (edges or area well defined by definite raising)	2
Edges well defined, but less than 1 mm	2.5
Moderate edema (raised approximately 1.0 mm)	3
Greater than 1 mm, exposure area only or 1 mm, extending beyond exposure area	3.5
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4

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A Division of Ralston Purina Company

REPORT

RICHARD J. HLAVKA
TWIN CITY TESTING
662 CROMWELL AVENUE
ST. PAUL, MN 55114

RT LAB NO. 896900
ENTERED 09/23/81
REPORTED 10/15/81

LIME SLUDGE: LAB #3029; SAMPLE #2

PURCHASE ORDER NUMBER C 3442

ENCLOSED:

PRIMARY DERMAL IRRITATION - METHOD, SUMMARY

RAW DATA ATTACHED

SIGNED: Gary W. Thompson
GARY W. THOMPSON, BS
MANAGER, ACUTE TOXICOLOGY

BY AND FOR RALTECH SCIENTIFIC SERVICES, INC.

Ratech
P.O. Box 7545 • Madison, Wisconsin 53707 • 608 241 4471
A Division of Ralston Purina Company

IME SLUDGE: LAB #3028; SAMPLE #2

RIM SKIN IRRITATION

TEST ANIMAL: YOUNG ADULT RABBITS (APPROXIMATELY 14 WEEKS OF AGE) OF THE NEW ZEALAND WHITE STRAIN WERE MAINTAINED INDIVIDUALLY IN SCREEN BOTTOM CAGES IN TEMPERATURE AND HUMIDITY CONTROLLED QUARTERS, PROVIDED CONTINUOUS ACCESS TO COMMERCIAL LABORATORY FEED AND WATER, AND HELD FOR AN ACCLIMATION PERIOD OF AT LEAST 7 DAYS.

THREE MALE AND THREE FEMALE ACCLIMATED ANIMALS WERE CHOSEN AT RANDOM FOR THE TEST, TREATED, AND MAINTAINED DURING THE OBSERVATION PERIOD AS SPECIFIED FOR THE ACCLIMATION PERIOD. TEST ANIMALS WERE IDENTIFIED BY ANIMAL NUMBER AND CORRESPONDING EAR TAG. TWENTY-FOUR HOURS BEFORE TREATMENT THE HAIR WAS CLIPPED FROM THE BACK AND FLANKS OF EACH ANIMAL.

PREPARATION AND CONCENTRATION OF TEST MATERIAL: AS SUBMITTED, IH DETERMINED TO BE APPROXIMATELY 12.0

TREATMENT: JUST BEFORE THE TEST MATERIAL WAS APPLIED, CRISSCROSS EPIDERMAL ABRASIONS WERE MADE ON ONE EXPOSED AREA OF EACH RABBIT TO PROVIDE ONE ABRADED AND ONE INTACT TEST SITE. (THE ABRASIONS WERE SUFFICIENTLY DEEP TO PENETRATE THE STRATUM CORNEUM, BUT NOT DEEP ENOUGH TO PENETRATE TO THE DERMAL LAYER AND CAUSE BLEEDING.)

THE TEST MATERIAL WAS APPLIED TO THE TWO TEST SITES ON EACH RABBIT IN THE AMOUNT OF 0.5 ML PER SITE. EACH TREATED AREA WAS COVERED WITH A 5.0 X 5.0 CM GAUZE PATCH SECURED WITH PAPER TAPE AND OVERWRAPPED WITH SARAN WRAP AND ELASTOPLAST TAPE TO MAINTAIN THE TEST MATERIAL IN CONTACT WITH THE SKIN AND DECREASE THE RATE OF EVAPORATION. COLLARS WERE APPLIED TO THE ANIMALS FOR THE 24-HOUR TREATMENT PERIOD.

OBSERVATIONS: AFTER TREATMENT THE PATCHES WERE REMOVED AND THE TEST MATERIAL WAS WIPED (NOT WASHED) FROM THE AREA AS THOROUGHLY AS POSSIBLE WITHOUT IRRITATING THE SKIN. THE DEGREE OF ERYTHEMA AND EDEMA WAS READ ACCORDING TO THE DRAIZE TECHNIQUE.* A SECOND READING WAS TAKEN AT 72 HOURS TO DETERMINE THE PRIMARY IRRITATION INDEX FOR THE SAMPLE.

PATHOLOGY: AT STUDY TERMINATION ALL ANIMALS WERE EUTHANATIZED AND DISCARDED.

*DRAIZE, J. H., 1959, APPRAISAL OF THE SAFETY OF CHEMICALS IN FOODS, DRUGS AND COSMETICS - DERMAL TOXICITY. ASSOCIATION OF FOOD AND DRUG OFFICIALS OF THE U.S., TOPEKA, KANSAS, PP. 49-51.

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IME SLUDGE: LAB #3026; SAMPLE #2

RIM SKIN IRRITATION(CONTINUED)
TEST ANIMAL: NEW ZEALAND WHITE STRAIN RABBITS
SOURCE: KUIPER'S RABBITRY, GARY, IN
DATE ANIMALS RECEIVED: 9/16/81
DATE TEST STARTED: 9/29/81 DATE TEST COMPLETED: 10/1/81

PRIMARY DERMAL IRRITATION SCORE	6 RABBIT MEAN
24 HOURS:	3.3
72 HOURS:	1.8

PRIMARY DERMAL IRRITATION INDEX:* 2.6

*THE PRIMARY DERMAL IRRITATION INDEX IS THE SUM OF THE 24 AND 72-HOUR PRIMARY DERMAL IRRITATION SCORES, DIVIDED BY TWO AND ROUNDED TO THE NEAREST TENTH.

CONCLUSION:
ACCORDING TO FHSA REGULATIONS, THIS COMPOUND IS NOT A PRIMARY SKIN IRRITANT.

COMMENTS:

ONE ANIMAL EXHIBITED BLANCHING OF THE ABRADED TEST SITE AT BOTH OBSERVATIONS AND SUBCUTANEOUS HEMORRHAGE OF THE SAME SITE AT 72 HOURS.

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ATTACHMENT I

SCALE FOR SCORING SKIN REACTIONS

Erythema and Eschar Formation:	Value
No erythema	0
Doubtful or barely perceptible	0.5
Very slight erythema	1
Slight, not well defined	1.5
Well defined erythema	2
Moderate	2.5
Moderate to severe erythema	3
Severe, not beet red	3.5
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Edema Formation:	
No edema	0
Doubtful or barely perceptible	0.5
Very slight edema	1
Slight, not well defined	1.5
Slight edema (edges or area well defined by definite raising)	2
Edges well defined, but less than 1 mm	2.5
Moderate edema (raised approximately 1.0 mm)	3
Greater than 1 mm, exposure area only or 1 mm, extending beyond exposure area	3.5
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4