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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polyol Ester NP-439

This Assessment has been compiled in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

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Director Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polyol Ester NP-439

1. **APPLICANT**

Exxon Chemical Australia Ltd of 12 Riverside Quay SOUTHBANK VICTORIA 3006, has submitted a standard notification statement with their application for an assessment certificate for Polyol Ester NP-439.

2. **IDENTITY OF THE CHEMICAL**

Polyol Ester NP-439 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and certain details pertaining to the use of Polyol Ester NP-439 have been exempted from publication in the Full Public Report and the Summary Report.

Other names: pentaerythritol ester

polyol ester

Trade name: NP-439 22

Method of detection the notified substance can be detected using and determination:

infrared spectroscopy (IR) and identified using gas

chromatography

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa:

light yellow liquid

Boiling point: the pour point determined as < -40°C; NP-439

decomposes at > 300°C (at 760 mm Hg)

Specific gravity: 0.963 g/mL at 24°C

4 x 10⁻⁶ kPa at 25°C Vapour pressure:

Water solubility: 0.06 mg/L at 20°C

Partition co-efficient estimated greater than 1.7 x 10⁸ (equivalent log₁₀

(n-octanol/water): $P_{ow} > 8.2$) (1) Hydrolysis as a function not determined; (Hydrolysis half-life > 1000 days;

of pH: ¹ASTER₋ calculated) (2)

estimated K_{oc} of 536000 (log K_{oc} = 5.73 -estimated Adsorption/desorption:

from log₁₀ P_{ow})(Log K_{oc} 8.49; ASTER calculated).

Dissociation constant: not determined

Flash point: closed 231°C

> open 287°C fire point 321°C

Flammability limits: non-flammable

Autoignition temperature: no ignition observed at 400°C

Explosive properties: not considered explosive

Reactivity/stability: not considered reactive

Comments on Physico-Chemical Properties

The notified liquid is relatively non-volatile and practically insoluble at room temperature. The negligible water solubility measured for this substance results from the lack of functionality that might confer such properties to this chemical.

While it contains ester linkages the notified substance is not expected to hydrolyse under the environmental conditions due to its low solubility, which also precludes measurement.

Due to the very low water solubility determined by the notifier, measurements of adsorption/desorption for NP-439 could not be made. Subsequently, an estimation of the ability for adsorption/desorption was made (Pharmaco LSR Report No: 95/ENE002/1173), which indicated the notified substance is expected to sorb strongly to soils. This is also indicated by its low water solubility and high log P. There are no groups likely to dissociate within this ester

The notified chemical is not considered reactive. It does not readily degrade or decompose, hazardous polymerisation will not occur.

⁻ It should be noted that ASTER calculations are based on theoretical models and have no experimental basis.

4. PURITY OF THE CHEMICAL

Degree of purity: > 98.5%

Toxic or hazardous

impurities:

none known

Non-hazardous impurities

(> 1% by weight):

< 2%

None of the listed impurities are listed in Worksafe Australia's *List of Designated Hazardous Substances* (3) and there are no entries in either Sax and Lewis (4) or Toxline (5).

Maximum content see non-hazardous impurities

of residual monomers:

Additives/Adjuvants: none, notified polymer will be imported as part of

an additive package; package is not classified as

hazardous according to criteria of Worksafe

Australia (notifier's classification)

5. USE, VOLUME AND FORMULATION

It is estimated that between 10-100 tonne of the notified substance will be imported over the next 5 years, to be used as a component of lubricating oils.

The notified substance will be imported in 200 kg steel drums and transported from dockside to various companies. No formulation of the notified product will be done in Australia.

6. OCCUPATIONAL EXPOSURE

The notified polymer is imported in 200 L steel drums as a component of lubricating oil.

Occupational exposure during transport and warehousing will only occur due to accidental spillage. Occupational exposure will be greatest during repackaging which will occur at the facilities of Exxon's customers. The lubricant formulation will be decanted from the 200 L steel drums into smaller containers up to 5 L in capacity. At no time is the imported formulation reformulated, neither is the notified polymer isolated. The repackaging is undertaken by plant operators who operate the valves and pumps of the automated repackaging equipment. 2-3 employees will be involved in this operation at each repackaging facility. In total, including maintenance workers, there will be fewer than 10 employees per site who will come into contact with the notified chemical through occupational exposure.

The main route of occupational exposure is likely to be through dermal contact. Exposure is most likely to occur when connections to the automated repackaging equipment are made and broken and during maintenance of the equipment. Eye contact may occur via splashing. Inhalational exposure is unlikely due to the low volatility of the notified chemical.

7. PUBLIC EXPOSURE

The notified chemical will not be manufactured in Australia. The notified chemical will be imported in 200 L steel drums as a component of lubricating oil. The notified chemical will be transported by road within Australia. At the customer facilities, the product will be repacked into consumer size containers (≤ 5 L). If accidental spillage occurs the oil containing the notified chemical will be contained and cleaned-up by saturation with earth or sand before incineration as recommended in the Material Safety Data Sheet (MSDS). No public exposure to Polyol Ester NP-439 is expected to occur during transport or repacking.

The public will come in contact with the notified chemical when filling engines.

Waste oil containing the notified chemical (residual in drums and spillage) will be either incinerated or placed in landfills.

8. ENVIRONMENTAL EXPOSURE

Release

Repackaging of the oil containing the notified substance into volumes of 5 litres or less will take place at the customer facility. The notifier has indicated that the maximum yearly loss from repackaging (eg. connection/disconnection and transfer losses) will be "slight and incidental" and of the order of millilitres due to the closed system nature of these processes. Possible release to the environment will be through cleaning of the 200 L import drums and spillages upon use of the oil. 0.35-0.69 L of residues per drum have been measured. These residues will be incinerated as waste solvent. Treatment and disposal of any spillages is adequately dealt with in the MSDS.

Environmental exposure during the use of the oil is likely. This is possible through spillages during filling.

Fate

As the notified substance is a lubricant component the majority of the notified substance released to the environment would be via emissions, with a minor component arising from spillage of the oil at either the repackaging or final use stages. The latter material will be collected as washes of the affected area and then disposal at an approved liquid waste disposal facility or collected and sealed in labelled drums suitable for landfill. In the case of washes, organic solvents such as alcohols or water-based detergents are used, with the washings captured in drums

for disposal according to local regulations.

In the event of incomplete combustion, the amount of specified substance estimated to be released to the atmospheric, terrestrial or aquatic environments is significant but would be widespread, low level and difficult to collect. Mackay level environmental partitioning data were estimated using the ASTER database and indicated that > 99% would partition in soils and sediments at 25 °C, with none remaining in the air compartment.

Biodegradation

The biodegradation of the notified substance has been determined to be negligible by the modified OECD screening test (6). This protocol determines the aerobic biodegradation potential of organic material by measuring the loss of dissolved organic carbon in these test systems over a period of 28 days. The notified adduct showed 65.0% biodegradation over the 28 day period which indicates the substance is not readily degradable. Note that the ASTER database indicates a BOD half-life of between 2 and 16 days, indicating the substance is not highly persistent, as suggested by significant extent of degradation in the ready biodegradation test.

Bioaccumulation

The waste generated by use of the notified substance will, in the general case, be oxides of carbon that will diffuse into the atmosphere. Given the biodegradability potential of NP-439 and its $\log_{10} P_{ow}$ value (> 8) the potential for bioaccumulation seems negligible, since a substance with a $\log P > 6.5$ is not taken up (7). The notified substance is unlikely to breakdown or remain in the air, but rather become adsorbed to the soil and sediments and thus not be available to biota, as supported by the ASTER calculated Mackay data.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Polyol Ester NP-439

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 2000mg/kg	8
acute dermal toxicity	rabbit	LD ₅₀ > 2000mg/kg	9
skin irritation	rabbit	non-irritant	12
eye irritation	rabbit	slight irritant	13
skin sensitisation	guinea pig	non-sensitiser	14

9.1.1 Oral Toxicity (8)

Species/strain: rat

Number/sex of animals M/F: 5/5

Observation period: 14 days

Method of administration: intubation of single dose of 2000 mg/kg

(undiluted, no carrier)

Clinical observations: 2 F showed anogenital staining at 4-6 hours

after administration

Mortality: none

Morphological findings: no effects noted

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

 LD_{50} : > 2000mg/kg

Result: low oral toxicity

9.1.2 Dermal Toxicity (9)

Species/strain: New Zealand white rabbit

Number/sex of animals M/F: 10/10

Observation period: 14 days

Method of administration: occluded patch to clipped skin; 24 hour

exposure; 2 groups 5/5 1900 mg/kg and 5/5

2000 mg/kg

Clinical observations: one animal in 1900 mg/kg group small/soft

stool and reduced food consumption, one rabbit in the 2000 mg/kg group had a nasal discharge on day 12. These observations were not thought to be treatment related.

Mortality: none

Morphological findings: at post mortem all 1900 mg/kg and two 2000

mg/kg animals had desquamation at test site

Draize scores (10):

Time after treatment	Animal # (2000mg/kg group)									
(days)	1	2	3	4	5	6	7	8	9	10
Erythema										
1	ⁱ 0	1	1	1	2	1	1	2	1	1
7	0	0_D	0	0 ^D	0 ^D	0	0	0 ^D	0	0 ^D
14	0	0	0	0	0	0 ^D	0	0	0	0 ^D
Oedema										
1	0	0	0	0	1	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0

i see Attachment 1 for Draize scales

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: low dermal toxicity, slight irritant; not classified

as hazardous (irritant) according to Worksafe Australia's *Approved Criteria for Classifying*

Hazardous Substances (11)

9.1.4 Skin Irritation (12)

Species/strain: New Zealand white rabbit

Number/sex of animals 6 males

Observation period: 72 hours

Method of administration: a neat sample of the notified chemical (0.5 ml)

was applied under an occluded dressing for 4

hours, area was then wiped

Draize scores (5): 0.00

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: non-irritant

9.1.5 Eye Irritation (13)

Species/strain: New Zealand white rabbit

Number/sex of animals M/F: 5/1

^D desquamation

Observation period: 7 days

Method of administration: 0.1 ml into conjunctival sac of one eye

Draize scores (5):

Time after instillation

Animal	1	hοι	ır	1	day	/	2	day	'S	3	day	'S	7	day	'S
Cornea	Oª	а	l ^b	O ^a	а	b	O ^a	a	l ^b	O ^a	a	b	Oª	ŧ	l ^b
1	10	C)	0	0)	0	C)	0	C)	0	C)
2	0	0)	0	0)	0	C)	0	C)	0	C)
3	0	0)	0	0)	0	C)	0	C)	0	C)
4	0	0)	0	0)	0	C)	0	C)	0	C)
5	0	0)	0	0		0	C)	0	0)	0	C)
6	0	0)	0	0		0	C)	0	0		0	C)
Iris															
1		0			0			0			0			0	
2		0			0			0			0			0	
3		0			0			0			0			0	
4		0			0			0			0			0	
5		0			0			0			0			0	
6		0			0			0			0			0	
Conjunctiva	r c	\boldsymbol{c}^d	d e	r c	c^d	d e	r c	c_q	d e	r c	c_q	d e	r c	c_q	ďe
1	2	2	3	1	0	0	0	0	0	0	0	0	0	0	0
2	2	1	3	0	0	0	1	0	0	1	0	0	0	0	0
3	2	1	3	0	0	0	0	0	0	0	0	0	0	0	0
4	1	2	3	0	0	0	0	0	0	0	0	0	0	0	0
5	3	2	2	1	0	0	1	0	0	0	0	0	0	0	0
6	2	3	3	1	0	0	1	0	0	1	0	0	0	0	0

i see Attachment 1 for Draize scales

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: conjunctival mean scores at 24 hours are

redness 0.5 and chemosis 0.0; therefore the

notified chemical is not classified as

hazardous (irritant) according to Worksafe Australia's *Approved Criteria for Classifying*

Hazardous Substances (11)

a opacity b area c redness d chemosis e discharge

9.1.6 Skin Sensitisation (14)

Species/strain: Hartley guinea pig

Number of animals: 20 test, 10 control all females

Induction procedure: three pairs of injections of 0.1 mL: FCA in

water; 5% notified chemical in peanut oil with and without FCA; topical induction: at day 7 by 0.5 mL 100% notified chemical for 48 hours

then wiped.

Challenge procedure: day 21 use of 50% v/v notified chemical

produced reactions in the controls which, while not suggestive of sensitisation, made scoring imprecise: a second challenge was conducted one week later using challenge concentrations of 10% notified chemical

Challenge outcome:

	Test a	nimals	Control	animals
Challenge concentration	24 hrs*	48 hrs*	24 hrs	48 hrs
50%	18/20	7/20	8/20	3/20
10%	**4/20	0/20	4/20	0/20

^{*} time after patch removal

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: at challenge of 50% test material erythema

was apparent in both treated and irritation control groups, this was considered an irritation response rather than a sensitisation

response; a rechallenge one week later with a reduced concentration of the test material (10%) gave a reduced response in test and control groups, no response evident at 48 hours; on this basis classified as non-

sensitiser

^{**} number of animals exhibiting positive response

9.2 Repeated Dose Toxicity (15)

Species/strain: rat

Number/sex of animals M/F: 3 dose regimes 5/5 per group, 5/5 control and

5/5 positive control (acrylamide)

Method of administration: single gavage daily

Dose/Study duration:: 100, 500 and 1000 mg/kg/day, 28 days

Clinical observations: no clinical signs

Clinical statistically significant reduction in serum

chemistry/Haematology calcium, protein and albumin in mid dose

males and an increase in alanine aminotransferase in low dose males

Histopathology/necropsy: mean testes weight increase in mid dose

males no other significant signs

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: no overt signs of systemic toxicity at any dose

level tested

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (16)

Strains: TA98, 100, 1535, 1537 and 1538

Concentration range: 0.5 - 5000 µg/plate with or without rat liver S9

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: non-mutagenic in S. typhimurium, controls

gave appropriate response

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary Cells (17)

Doses: mutagenicity: 5-160 µg/ml

with and without metabolic activation

Method of administration: In vitro study, cells maintained in McCoy's 5A

medium supplemented with foetal calf serum

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: no relevant increase in mutant frequencies

with or without metabolic activation at maximum dose, controls gave appropriate

response

9.3.3 In Vivo Mammalian Bone Marrow Micronucleus Assay (18)

Species/strain: CDI mice

Number/sex of animals M/F: 3 dose regimes 5/5 per group, 5/5 control (

peanut oil) and 5/5 positive control (20 mg/kg

cyclophosphamide)

Method of administration: single gavage daily

Dose/Study duration:: 500, 1000 and 2000 mg/kg, dose volume did

not exceed 1 mL/100 g/bw, 3 treatments 24

hours apart

Clinical observations: no clinical signs

Test method: appears to conform to OECD Guidelines for

Testing of Chemicals

Result: no dose-related or significant increases in

micronuclei formation; cytotoxicity was not

observed

9.4 Other Toxicological Studies

In a developmental toxicity study using mice (19) there was no treatment related mortality, evidence of foetotoxicity, foetal growth retardation or significant variation in foetal malformities from pregnant females dosed with the notified chemical from day 6 to day 15 of gestation. The rats were dosed daily by gavage at either 100, 500 or 1000 mg/kg.

9.5 Overall Assessment of Toxicological Data

The notified polymer produced few toxic effects in a range of *in vitro* and *in vivo* assays. It has a low oral toxicity to rats ($LD_{50} > 2000 \text{ mg/kg}$), low dermal toxicity in rabbits ($LD_{50} > 2000 \text{ mg/kg}$), is not a skin irritant in rabbits or a skin sensitiser in guinea pigs. It was slight eye irritant to rabbits but the Draize scores were below the threshold for hazardous classification according to the criteria of Worksafe Australia (11).

In a 28-day repeat dose study in rats some effects on clinical chemistry/haematology were apparent but did not appear to be dose related. There were no overt signs of systemic toxicity at doses up to 1000 mg/kg/day.

The notified chemical was not mutagenic to *S. typhimurium* with or without metabolic activation. It was not clastogenic in a Chinese hamster ovary cell *in vitro* test. In an *in vivo* mammalian bone marrow micronucleus assay no doserelated or significant increases in micronuclei formation were observed. In a developmental toxicity study in mice there were no effects on foetal development or mortality at dose rates up to 1000 mg/kg/day.

On the basis of the toxicity data summarised above the notified polymer would not be classified as hazardous according to the criteria of Worksafe Australia (11).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. The tests were carried out to OECD Test Methods.

Test	Species	Results (Nominal WAF*)
Acute Renewal Toxicity	Fathead minnow (Pimephales promelas)	96 h LC ₅₀ > 4.11 mg/L
Acute Immobilisation/ Reproduction	Daphnid (<i>Daphnia magna</i>)	48 h EL ₅₀ > 1000 mg/L
Acute Growth Inhibition	Alga (Selenastrum capricornutum)	No effect at 1000 mg/L after 72 h
Microtox [©] Toxicity	Photobacterium phosphoreum	EL ₅₀ > 1000 mg/L for 5 and 15 min intervals

^{*} WAF = water accommodated fractions, except for the fish test.

For the toxicity tests on fathead minnow, ethanol was used to allow solubilisation of the notified substance to concentrations required for the OECD tests. For the other three toxicity investigations water accommodated fractions (WAF) were prepared for each concentration indicated below, with excess solid filtered off prior to the study, leaving a clear solution for testing.

Acute toxicity was tested on fathead minnow, but because of the low water solubility of the notified substance, five concentrations of 4.11 mg/L, 2.15 mg/L, 1.30mg/L, 0.85 mg/L and 0.24 mg/L were prepared using ethanol. During 96 hr periods of exposure of the notified substance to fathead minnow, no mortality was observed at any concentration and the LC_{50} value.

Acute immobilisation was tested by exposure of *Daphnia* to the notified substance according to OECD guideline 202. The WAF used were 1000 mg/L, 500 mg/L, 125

mg/L and 62.5 mg/L. The 48 hr EL_{50} (effective loading¹) for these tests were > 1000 mg/L.

Alga test growth inhibition was carried out on *Selenastrum capricornutum* using OECD guideline 201. WAF were prepared for five exposure loadings, as for the *Daphnia*, which resulted in a calculated 72 hr NOEL (No Effect Observed Loading) of 1000 mg/L.

Non-toxic effects were indicated by the Microtox $^{\odot}$ system, representing growth of alga, in the presence of the notified substance, at WAF levels of 1000 mg/L, 500 mg/L, 250 mg/L and 125 mg/L. Light readings measured at 5 and 15 minute intervals indicated an EL₅₀ > 1000 mg/L.

The levels measured by the above tests, suggest this fatty acid ester would be considered non-toxic to the organisms tested, up to the level of its solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified substance is unlikely to present a hazard to the environment at any stage of its use. Of the original quantity of NP-439 imported (between 10-100 tonnes in the first 5 years) it is expected that negligible amounts will be released from the repackaging sites. The ultimate fate of the waste oil is treatment by incineration or by landfill at an approved industrial facility. Leaching of such treated wastes into the soil is not expected.

End-use release of the notified substance, together with spills occurring during addition, is likely to result in widespread but low level exposure. Together with a low order of ecotoxicity, a low impact on aquatic organisms, low aqueous solubility and a high level of biodegradability the potential hazard to the environment should be negligible and use characteristics are generally supported by the literature (8).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is only imported as a component of a formulation that will be sold direct to Exxon's customers. The formulation will not be reformulated, but repackaged and the notified chemical will never be isolated.

The notified chemical and the formulation in which it is imported are not classified as hazardous according to the criteria of Worksafe Australia. The notified chemical has a low oral and dermal toxicity in studies using rats and rabbits. In a study using guinea pigs it was found not to be a skin sensitiser. In a study to determine eye irritancy potential in rabbits it was found to be a slight eye irritant but the level of irritancy was below that at which the notified chemical would be classified as hazardous. The notified chemical was not clastogenic in both *in vivo* and *in vitro*

¹ Effective loading is the calculated loading level which results in 50% immobilisation in a population during a specified exposure period.

studies.

Occupational, exposure during warehousing and transport is only likely to occur if the imported formulation is accidentally released. Occupational exposure will be greatest during repackaging. The formulation is imported in 200 L steel drums from which the oil is decanted using automated equipment and packaged into smaller containers of up to 5 L capacity. Exposure is likely to occur when connections from the 200 L drums are made and broken and during maintenance. The main occupational exposure pathway will be via dermal exposure. The low volatility of the notified polymer will limit inhalational exposure. Eye exposure may occur due to splashing.

On the basis of the toxicity data provided and the physico-chemical nature of the chemical the risks involved in occupational exposure to the notified chemical are considered to be low.

Under normal conditions of use, there is the potential for significant public exposure to the notified chemical since it will be used in lubricant which is sold direct to the public. Dermal contact with the notified chemical is the most likely route of exposure. Potential health hazards arising from acute exposure are anticipated to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to Polyol Ester NP-439 the following guidelines and precautions should be observed:

- during repackaging operations involving possible contact with chemical formulations containing the notified polymer to wear chemical-type goggles (selected and fitted according to Australian Standard (AS)1336 (20) and meeting the requirements of Australian/New Zealand Standard (AS/NZS) 1337 (21)), impermeable gloves (AS 2161) (22) should be worn to protect against unforseen circumstances.
- safe practices, as should be followed when handling any chemical formulation, should be adhered to - these include:
 - minimising spills and splashes;
 - practising good personal hygiene; and
 - practising good housekeeping and maintenance; including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal.
- It is expected that, in the industrial environment, protective clothing conforming to and used in accordance with AS 2919 (23) and protective footwear conforming to AS/NZS 2210 (24) should be worn as a matter of course.

a copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (25).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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- 17. Przygoda R T 1995, *Project Number 121632 In vitro chromosomal aberration assay in chinese hamster ovary (CHO) cells, test performed on NP-439*, Exxon Biomedical Sciences Inc., East Millstone, USA.
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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	Rating	Oedema Formation	Rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well- defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	Rating	Area of Cornea involved	Rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible Diffuse beefy red	3	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and	3 severe
	severe	Swelling with lids half-closed to completely closed	4 severe	hairs and considerable area around eye	

IRIS

Values	Rating
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe