

[FOREWORD](#)

[INTRODUCTION](#)

NICOTINIC ACID
CAS N°: 59-67-6

Substance

<i>End Point</i>	:	IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES
<i>Chemical Name</i>	:	3-Pyridinecarboxylic acid
<i>Common Name</i>	:	Nicotinic acid
<i>CAS Number</i>	:	59-67-6
<i>RTECS Number</i>	:	QT0525000

Synonyms

Acotin	Apelagnin
3-Carboxypyridine	3-Carboxypyridine
Daskil	Efacin
Linic	Niacine
Nicacid	Nicangin
Nicobid	Nicodelmine
Nicolar	Niconacid
Nicosan 3	Nico-span
Nicotene	Nicotinipca
Nicyl	Nyclin
Pellagrin	Pelonin
Pyridine-.beta.-carboxilic acid	PP-factor
m-pyridinecarboxilic acid	Tinic
Wampocap	

Properties & Definitions

<i>Molecular Formula</i>	:	C6H5NO2
<i>Molecular Weight</i>	:	123.11
<i>Melting Point</i>	:	236.6C
<i>Boiling Point</i>	:	>238C
<i>State</i>	:	Solid, non-hygroscopic
<i>Density</i>	:	1.473g/cm3
<i>Vapour Pressure</i>	:	<0.01kPa (0.75mmHg) at 20C CAL
<i>Octanol/Water Partition Coefficient</i>	:	log Pow = -0.59; pH4,25C; -2.34; pH7,25C
<i>Water Solubility</i>	:	15g/l at 20C
<i>General Comments</i>	:	According to EEC directive 67/548 no classification and labelling for nicotinic acid are required. With respect to transport nicotinic acid is a non-dangerous good.

Overall Evaluation

SIDS INITIAL ASSESMENT

This chemical is presently of low priority for further work.

HUMAN HEALTH

Nicotinic acid is a vitamin essential for human and animal health. The daily requirement to avoid deficiencies in humans is in the range of 15 to 40 mg. For therapeutical purposes daily doses up to 6000mg are used.

Nicotinic acid is actually not toxic, but moderately irritant to the eye. Rare cases of skin flushing may occur, but this effect is reversible after termination of exposure.

The no observed adverse effect level (NOAEL) in a 28-day oral study in rats was 50mg/kg/day. However, only a minimal effect on body weight gain without any organ toxicity was found up to the high dose of 1000mg/kg/day.

For an initial assessment the estimated dose of low concern (EDLC) can be compared with the estimated

human exposure (EHE):

$$\text{EDLC} = \text{NOAEL}/\text{UF} = 50/100 = 0.5\text{mg/kg/day}$$

The uncertainty factor (UF) of 100 is based on intraspecies variation (factor of 10) and interspecies variation (factor of 10). As the only effect seen at higher dose levels (250 and 1000mg/kg/day) was a slight reduction of the body weight gain a UF of 100 is considered to be sufficient.

The EHE for occupational exposure (EHEocc) can be calculated based on the maximum average concentration measured in the room where the bags are filled: 2mg/m³.

$$\text{EHE}_{\text{occ}} = 10\text{m}^3 \times 2\text{mg}/\text{m}^3/70\text{kg} = 0.29\text{mg/kg/day}$$

Respiratory volume per working day (8h) : 10m³

Weight of an adult : 70kg

The EHE for the general population (EHEgp) can be calculated based on the estimated air concentration in the vicinity of the plant : 2.2 x 10E-4mg/m³.

$$\text{EHE}_{\text{gp}} = 30\text{m}^3 \times 2.2 \times 10\text{E-}4\text{mg}/\text{m}^3/70\text{kg} = 0.9 \times 10\text{E-}4\text{mg/kg/day}$$

Assumed daily respiratory volume of the general population : 30m³

Weight of an adult : 70kg

$$\text{EDLC}/\text{EHE}_{\text{occ}} = 0.5/0.29 = 1.7$$

$$\text{EDLC}/\text{EHE}_{\text{gp}} = 0.5/0.9 \times 10\text{E-}4 > 5000$$

Furthermore a carcinogenicity study in mice showed no carcinogenic effects.

Nicotinic acid is not teratogenic up to 1000mg/kg/day. The no effect level for maternal toxicity is 200mg/kg/day.

The EDLC/EHE can be calculated as follows:

$$\text{EDLC}_{\text{maternal toxicity}} = \text{NOAEL}/\text{UF} = 200/100 = 2$$

$$\text{EDLC}_{\text{developmental toxicity}} = \text{NOAEL}/\text{UF} = 1000/100 = 10$$

$$\text{EDLC}_{\text{maternal toxicity}}/\text{EHE}_{\text{occ}} = 2/0.29 = 7$$

$$\text{EDLC}_{\text{maternal toxicity}}/\text{EHE}_{\text{gp}} = 2/0.9 \times 10\text{E-}4 > 20'000$$

$$\text{EDLC}_{\text{developmental toxicity}}/\text{EHE}_{\text{occ}} = 10/0.29 = 35$$

$$\text{EDLC}_{\text{developmental toxicity}}/\text{EHE}_{\text{gp}} = 10/0.9 \times 10\text{E-}4 > 100'000$$

CONCLUSION

Based on this information it can be concluded that nicotinic acid does not present a hazard to human health.

ENVIRONMENT

Nicotinic acid is practically non toxic to aquatic organisms. The lowest EC50 value was observed in daphnia : 77mg/l. According to the OECD provisional guidance for the initial assessment of aquatic effects an assessment factor of 100 is applicable. Based on these data the maximum tolerable concentration (MTC) can be calculated:

$$\text{MTC} = 77\text{mg}/\text{l}/100 = 0.77\text{mg}/\text{l}$$

A comparison of the MTC with the PEC (worst case) = 1.4 x 10E-6mg/l gives the following result:

$$\text{MTC}/\text{PEC (worst case)} = 0.77/1.4 \times 10\text{E-}6 = 5.5 \times 10\text{E+}5$$

CONCLUSION

Based on the MTC/PEC ratio the substance is considered to be of low concern to the aquatic environment. It is not toxic to bacteria and completely biodegradable. Therefore a complete elimination of nicotinic acid is likely to occur in the waste water treatment plant. No bioaccumulation is expected.

CONCLUSIONS AND RECOMMENDATIONS

Based on the available information it can be concluded that nicotinic acid does not present a hazard to human health or the environment.

No need for further testing or information gathering.

Production-Trade

Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**
Geographic Area : **EUR**
Area Specifications : **W**

Production

Quantity Year

10000 T - P

General Comments : No information given on years of production.

References

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

37EDAJ

Ullmanns Encyklopaedie der Technischen Chemie., 23, (1983)

Production-Trade

Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**
Geographic Area : **USA**

Production

Quantity Year

1000 T - P

General Comments : No information given on years of production.

References

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

37EDAJ

Ullmanns Encyklopaedie der Technischen Chemie., 23, (1983)

Production-Trade

Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**
Geographic Area : **ASIA**
Area Specifications : **E**

Production

Quantity

Year

1000 T - P

General Comments : No information given on years of production.

References

!SIDSP*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

37EDAJ

Ullmanns Encyklopaedie der Technischen Chemie., 23, (1983)

Processes

Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Process

Process comments : Nicotinic acid is industrially produced from nicotinonitril which is usually obtained from oxidation of nicotine with concentrated HNO₃. It can also be obtained from oxidation of alkyl .beta.-substituted pyridines.

References

Primary Reference : **IECHAD**
Woodward et al. Industrial and Engineering Chemistry, 36, 540, (1944)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Uses

Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Use

<u>Quantity</u>	<u>Year</u>	<u>Comments</u>
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Nicotinic acid is a vitamin and is used for food and feed applications as an essential component of food stuff for a balanced diet requirements.

References

Secondary References : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **Pathway into the Environment and Environmental Fate.**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Pathway and Transport

Pathway : **INDST**

Quantity Transported

<u>Medium</u>	<u>to Medium</u>	<u>Quantity</u>	<u>Time</u>	<u>Year</u>	<u>to Year</u>
	to AIR	250 g/h			
Released to air from exhaust sources					
	to AQ	250 g/d			
Released into waste water leaving the production plant					

References

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, (1993)

Study

End Point : **CONCENTRATION**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Species/strain/system : Factory air measured in the filling room.

Test Method and Conditions

Test method description : Production site concentration measured using Sartorius Gravikon with glass fibres filter type SM 13,400. Environmental concentrations were calculated.

Test Results

Matrix Concentrations Spec. Date

AIR **2.2E-4 mg/m3**

Estimated in air, taking into account the local geographic and climatic conditions. (Considered layer: 200m; valley width: 800m; wind speed: 2m/s and 250g/h of nicotinic acid released into air).

AQ **1.388E-6 mg/l**

Predicted environmental concentration (PEC) in water: (dilution in the waste water treatment plant and biodegradation processes not considered).

AIR **<1-2 mg/m3**

AV

Measured in the room of filling at the production site, at a height of 1.6m. (Equipment: Sartorius Gravikon with glass filter, type SM 13400) concentrations depending on the distance from the filling line.

References

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **BIODEGRADATION**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**
Study type : **LAB**

Test Subject

Organism Medium Specification

AQ

Species/strain/system : Water

Test Substance

Purity Grade : **99.8%**

Test Method and Conditions

Test method description : OECD Guideline 301E (Modified screening test). GLP: YES

(An)aerobic : **AEROB**

Test Results

<u>Quantity</u>	<u>Time</u>
100 %	14 d

References

Primary Reference : **#URRCC***
RCC, Unpublished Report, (1990)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 4, (1993)

Study

End Point : **BIODEGRADATION**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism Medium Specification

SOIL

Species/strain/system : Aerobic soil suspension

Test Method and Conditions

Test method description : GLP: NO

(An)aerobic : **AEROB**

Test Results

Quantity Time

79 % **3 d**

References

Primary Reference : **ECTCDK**
Environmental Toxicology and Chemistry, 5, 503-509, (1986)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **BIODEGRADATION**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**
Study type : **LAB**

Test Subject

Organism Medium Specification

SOIL

Species/strain/system : Soil suspension (aerobic and anaerobic)

Test Method and Conditions

Test method description : GLP: NO. Tested in tightly closed tubes for anaerobic degradation.

Test Results

Quantity Time Comments on result

100 % **2-4 d** Under aerobic test conditions.

100 % **32-66 d** Under anaerobic test conditions.

References

<i>Primary Reference</i>	:	SBIOAH Soil Biology and Biochemistry, 4, 313-323, (1972)
<i>Secondary Reference</i>	:	!SIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)

Study

<i>End Point</i>	:	BIODEGRADATION
<i>Chemical Name</i>	:	3-Pyridinecarboxylic acid
<i>CAS Number</i>	:	59-67-6
<i>Study type</i>	:	LAB

Test Subject

Organism Medium Specification

AQ
SED

Species/strain/system : Anaerobic water-sediment

Test Method and Conditions

Test method description : GLP: NO

(An)aerobic : **ANAER**

Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
94 %	1 mo	Sulfate red slurry
94 %	1 mo	Methanogenic slurry

References

<i>Primary Reference</i>	:	ECTCDK Environmental Toxicology and Chemistry, 8, 1149-58, (1989)
<i>Secondary Reference</i>	:	!SIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)

Study

End Point : **HYDROLYSIS**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Results

<u>Quantity</u>	<u>Time</u>	<u>Comments on result</u>
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Ka: 1.50 x E-5

Kb: 1.04 x E-12

References

Primary Reference : **TFSOA4**
Evans, R. F. et al. Transactions of the Faraday Society, 49, 1284, (1953)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 5, (1993)

Study

<i>End Point</i>	:	BIOCONCENTRATION
<i>Chemical Name</i>	:	3-Pyridinecarboxylic acid
<i>CAS Number</i>	:	59-67-6

Evaluations

<i>Evaluation text</i>	:	No bioaccumulation expected based on the low Log Pow (-2.34 at 25C and pH7).
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References

<i>Secondary Reference</i>	:	!SIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5, (1993)
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Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Species/strain/system : Wistar rats
Exposure Type : **ACUTE**
Dose / Concentration : **5000 mg/kg BW**

Test Method and Conditions

Test method description : Limit test; OECD Guideline 401; GLP: YES

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			ORL			LD50	LD50 was determined as higher than 5000mg/kg/body weight - which was the highest dose tested.
<i>General Comments</i>		:	There was no mortality at all doses and no substance related symptoms.				

References

Primary Reference : **#HAZUR***
 Hazelton, Unpublished Report, (1981)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 7, (1993)

Study

End Point : **MAMMALIAN ACUTE TOXICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Species/strain/system : Wistar rats
Dose / Concentration : **2000 mg/kg BW**

Test Method and Conditions

Test method description : Limit test; OECD Guideline 402.

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
RAT			ORL			LD50	The dose up to 2000mg/kg (the highest dose in the test) was determined as dermal LD50.
<i>General Comments</i>		:	There was no mortality and no symptoms reported.				

References

- Primary Reference* : **#URRCC***
RCC, Unpublished Report, (1983)
- Secondary Reference* : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, 7, (1993)
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Study

End Point : MAMMALIAN TOXICITY
 Chemical Name : 3-Pyridinecarboxylic acid
 CAS Number : 59-67-6

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
RAT			ORL		M F	5/GROUP 5/GROUP	

Species/strain/system : Crl: CD (SD) BR rats

Test Substance

Purity Grade : 99.5%

Test Method and Conditions

Test method description : OECD Guideline 407; Repeated Dose Toxicity test; GLP: YES

Exposure

Dose / Concentration : 50-1000 mg/kg /d
 Exposure comments : Doses of 50, 250 and 1000mg/kg/day were given to determine systemic toxicity in 28 day dietary study. Five males and five females per dosage group were examined at necropsy.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
	NEF				

No mortality and no evidence of systemic toxicity were observed up to the high dose.

BW RETAR

Slight reduction of body weight gain was observed in 250 and 1000mg/kg/body weight per day groups.

NOEL

No Observed Effect Level was established to be 50mg/kg/day.

General Comments : Nicotinic acid is not toxic by repeated exposure.

References

Primary Reference : #HAZUR*
 Hazelton, Unpublished Report, 733, (1988)

Secondary Reference : !SIDSP*
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 8, (1993)

Study

End Point : **CARCINOGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**

Test Subject

<u>Organism</u>	<u>Medium</u>	<u>Specification</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Number exposed</u>	<u>Number controls</u>
MOUSE			ORL		M	50	
					F	50	

Species/strain/system : Swiss albino mice

Exposure

Dose / Concentration : **81-107 mg/kg BW**
 Exposure comments : Carcinogenicity study in Swiss albino mice with life time exposure to 1% nicotinic acid in drinking water. The daily dose = 81mg for female mice, 107mg for male mice.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
	NEF				

No carcinogenic effects were found.

General Comments : Nicotinic acid was not carcinogenic under the test conditions.

References

Primary Reference : **ANTRD4**
 Anticancer Research, 2, 71-74, (1982)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 11, (1993)

Study

End Point : **MUTAGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

BACT

Species/strain/system : Salmonella typhimurium TA1535, TA1537, TA1538, TA98, TA100

Test Substance

Purity Grade : **99.5%**

Test Method and Conditions

Test method description : OECD Guideline 471; Ames test; GLP: YES

Exposure

Dose / Concentration : **=<10 mg /plate**
Exposure comments : Mutagenic potential was tested in Ames test with maximum concentration of 10mg/plate with and without metabolic activation.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
NEF					

No mutagenic effects were observed with and without metabolic activation.

NEF

No toxicity to bacteria were observed.

General Comments : There are three other sets of tests reported in SIDS data on the mutagenic potential of test substance and all demonstrated negative results. Under the test conditions 3-pyridinecarboxylic acid does not induce mutagenicity.

References

Primary Reference : **#URIRI***
 IRI, Unpublished Report, 3026, (1984)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5-8, (1993)

Study

End Point : **MUTAGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**
 Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

BACT
FUNGI

Species/strain/system : Salmonella typhimurium TA1535, TA1537, TA1538, TA98, TA100.
Saccharomyces cerevisiae, strain D4.

Test Substance

Impurities : **Purity not specified**

Test Method and Conditions

Test method description : GLP: NO. Test with and without metabolic activation.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in</u> <u>Exposed - Controls</u>
-----	-----	-----	-----	-----	-----
NEF					
No mutagenic activity.					

References

Primary Reference : **LITTR***
Litton Report, (1977)

Secondary Reference : **!SIDSP***
Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**
 Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

BACT

Species/strain/system : Salmonella typhimurium

Test Substance

Impurities : **Purity not specified**

Test Method and Conditions

Test method description : Ames test with and without metabolic activation

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
NEF					
No mutagenic effects					

References

Primary Reference : **FDCHT***
FD Chemical Toxicology, 22, 623-636, (1984)

Secondary Reference : **!SIDSP***
Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism *Medium* *Specification* *Route* *Lifestage* *Sex* *Number exposed* *Number controls*

FUNGI

Species/strain/system : Saccharomyces cerevisiae D5

Test Substance

Purity Grade : **99.5%**

Test Method and Conditions

Test method description : Mitotic recombination in yeast, GLP: YES

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
NEF					
3-Pyridinecarboxylic acid does not induce mitotic recombination in yeast under test conditions.					

References

Primary Reference : **#URIRI***
IRI, Unpublished Report, 4022, (1985)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

HAMST

VTR

Species/strain/system : Chinese hamster ovary cells

Test Method and Conditions

Test method description : OECD Guideline number 473 - chromosomal aberration assay with and without metabolic activation. GLP: YES.

Exposure

Dose / Concentration : **=<5000 ug/ml**
Exposure comments : Doses up to 5000ug/ml were tested.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	NEF				

No mutagenic effect found on this chromosomal aberration assay up to 5000ug/ml.

References

Primary Reference : **#URIRI***
IRI, Unpublished Report, 4114, (1986)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 5-9, (1993)

Study

End Point : **MUTAGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

HAMST

VTR

Species/strain/system : Chinese hamster fibroblasts

Test Method and Conditions

Test method description : Chromosome aberration potential in mammalian cells.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
NEF					

No chromosomal aberrations observed under the test conditions.

References

Primary Reference : **FDCHT***
FD Chemical Toxicology, 22, 623-636, (1984)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **MUTAGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

MOUSE

ORL

Exposure

Exposure Type : **SHORT**
 Exposure comments : Mouse micronucleus test.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
NEF					

Test substance was negative for clastogenic effects.

References

Primary Reference : **FDCHT***
FD Chemical Toxicology, 26, 487-500, (1988)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, (1993)

Study

End Point : **MUTAGENICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT **ORL**

Species/strain/system : CD rats

Test Substance

Purity Grade : **99.5%**

Test Method and Conditions

Test method description : OECD Guideline number 475: cytogenic study; GLP: YES.

Exposure

Dose / Concentration : **5000 ug/ml**
Exposure comments : Rat bone marrow cytogenic assay with the dose of 5000ug/ml.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
BMW	NEF				

No chromosomal aberrations up to the dose of 5000ug/ml. No toxicity observed up to 5000ug/ml.

References

Primary Reference : **#URIRI***
IRI, Unpublished Report, 4055, (1985)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
Production Volume Chemicals Programme, (1993)

Study

End Point : **MUTAGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT

VTR

Species/strain/system : Rat hepatocytes

Test Method and Conditions

Test method description : OECD Guideline number 482; GLP: YES. Rat hepatocyte primary culture to test unscheduled DNA synthesis.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
DNA	NEF				
No unscheduled DNA synthesis observed.					

References

Primary Reference : **#URIRI***
 IRI, Unpublished Report, 4070, (1985)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

Study

End Point : **SENSITIZATION**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

GPIG **SKN** **ADULT**

Species/strain/system : Pirbright white guinea pigs

Test Method and Conditions

Test method description : OECD 406 Maximization test; GLP: NO

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	NEF				

No sensitization effect found.

References

Primary Reference : **#URAST***
 ASTA-Werke AG, Unpublished Report, (1986)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 8, (1993)

Study

End Point : IRRITATION
 Chemical Name : 3-Pyridinecarboxylic acid
 CAS Number : 59-67-6

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RBT SKN 6

Species/strain/system : New Zealand white rabbit

Test Substance

Purity Grade : 99.5%

Test Method and Conditions

Test method description : CFR title 49, part 173, 1976

Exposure

Exposure comments : 6 animals were tested for 4 hours exposure under occlusion on abraded and intact skin.

Test Results

<u>Organ</u>	<u>Effect</u>	<u>Rev.</u>	<u>OnSet</u>	<u>Sex</u>	<u>Affected in Exposed - Controls</u>
SKIN	NEF				

No irritation at any observation time. Primary irritation index: 0.0 (non irritant).

General Comments : The substance is negative for skin irritation potential.

References

Secondary Reference : ISIDSP*
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
 Production Volume Chemicals Programme, 7, (1993)

Study

End Point : IRRITATION
 Chemical Name : 3-Pyridinecarboxylic acid
 CAS Number : 59-67-6
 Study type : LAB

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RBT OCU

Species/strain/system : New Zealand white rabbits

Test Substance

Purity Grade : **99.9%**

Test Method and Conditions

Test method description : OECD Guideline number 405; GLP: YES. Testing was performed to determine eye irritation potential.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
EYE	IRRIT				

After 24h the maximum scores = 4.67 (mean cumulative score). Primary irritation index = 4.17 (moderate irritant)

General Comments : The substance was classified as moderate eye irritant.

References

Primary Reference : **#URRCC***
RCC, Unpublished Report, 274544, (1990)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 7, (1993)

Study

End Point : **TERATOGENICITY**
 Chemical Name : **3-Pyridinecarboxylic acid**
 CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

RAT **ORL** **F** **22/GROUP**

Species/strain/system : CD-Sprague Dawley, pregnant rats

Test Substance

Vehicle - Solvent : Aqueous methylcellulose 0.5%(w/v)

Test Method and Conditions

Test method description : FDA/EEC, GLP: YES

Exposure

Exposure Period : **6-15 TDP**
Dose / Concentration : **40-1000 mg/kg /day**
Exposure comments : Test substance was given in oral gavage at dose levels of 40, 200 or 1000mg/kg/day to groups of 22 pregnant rats from day 6 to day 15 of gestation. On day 20 of gestation, all animals were killed and the uterine contents were examined.

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
BW	RETAR				
Body weight gain in females receiving 1000mg/kg/day was slightly depressed.					
FETUS	SIZE				
Fetal weights were slightly lower at the dose level of 1000mg/kg/day of maternal exposure.					
PLCNT	SIZE				
Placental weights were slightly lower in rats receiving 1000mg/kg/day.					
NAEL					
No adverse effect level was established at 200mg/kg/day for dams and fetuses.					
<i>General Comments</i>	Under the test conditions nicotinic acid in oral administration to pregnant rats during the period of organogenesis at doses up to 200mg/kg/day was without adverse effects. At 1000mg/kg/day maternal body weight gain, placental and fetal weights were slightly depressed. No effect on survival, on litter size nor morphological changes upon "in utero" development were observed				

References

Primary Reference : **#URLZA***

Lonza, Unpublished Report/Result, (1992)

Secondary Reference : **!SIDSP***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 11, (1993)

Study

End Point : **AQUATIC ACUTE TOXICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Species/strain/system : Brown trout (Salmo trutta)
Exposure Period : **96 h**
Dose / Concentration : **520 mg/l**

Test Method and Conditions

Test method description : OECD Guideline 203

Test Results

<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	<u>Effect Comments</u>
FISH	AQ	MARIN				LC50	LC50 = 520mg/l for 96h exposure.

References

Primary Reference : **#URRCC***
 RCC, Unpublished Report, 023916, (1984)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

ALGAE AQ FRESH

Species/strain/system : Green algae (*Scenedesmus subspicatus*)

Test Method and Conditions

Test method description : OECD Guideline 201; DIN 38412L9. GLP: NO

Exposure

Exposure Period : **72 h**
Dose / Concentration : **90-100 mg/l**

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
POPUL	INHIB EC50				

Effective concentration for growth inhibition for 72h = 90mg /l (reported as EbC50)

POPUL **NEF**
EC0

Maximum concentration at which no effect was observed within 72h: EC0 = 25mg/l

POPUL **INHIB**

Minimum concentration at which effect was observed within 72 h: EC10 = 30mg/l (EuC10 = 38mg/l also reported)

General Comments : The growth inhibition was concentration and pH dependent.

References

Primary Reference : **#NOACK***
 NOACK Lab., Unpublished Report, (1989)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

BACT

Species/strain/system : Pseudomonas putida

Test Method and Conditions

Test method description : Bringmann-Kuehn GLP: NO

Exposure

Dose / Concentration : **120 mg/l**

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	EC50				
EC50 = 120mg/l					

References

Primary Reference : **#URBSF***
 BASF, Unpublished Report, 1074/89, (1989)

Secondary Reference : **!SIDSP***
 OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **AQUATIC TOXICITY**
Chemical Name : **3-Pyridinecarboxylic acid**
CAS Number : **59-67-6**
Study type : **LAB**

Test Subject

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

CRUS AQ FRESH

Species/strain/system : Water flea (Daphnia magna)

Test Method and Conditions

Test method description : OECD Guideline 202

Exposure

Exposure Type : ACUTE
Exposure Period : 3-48 h
Dose / Concentration : 77-580 mg/l

Test Results

<i>Organ</i>	<i>Effect</i>	<i>Rev.</i>	<i>OnSet</i>	<i>Sex</i>	<i>Affected in Exposed - Controls</i>
-----	-----	-----	-----	-----	-----
	BEHAV				
	EC50				

Effective concentration for 48h immobilization = 77mg/l

BEHAV

Control (pH 7.68): immobilization 0% (3h) - 5% (48h); at 580mg/l (pH 7.38 neutralized) immobilization 0% (3h) - 10% (48h); at 580mg/l (pH 3.95): immobilization 100% (3h) - 100% (48h)

General Comments : The immobilization was concentration and pH-dependent. Based on the calculated MTC/PEC ratio, nicotinic acid is considered to be of low concern to the aquatic environment.

References

Primary Reference : **#NOACK***
NOACK Lab., Unpublished Report, (1989)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Study

End Point : **TERRESTRIAL ACUTE TOXICITY**

Chemical Name : **3-Pyridinecarboxylic acid**

CAS Number : **59-67-6**

Species/strain/system : House sparrow, Quail (Coturnix, coturnix)

Test Method and Conditions

Test method description : U.S. Fish and Wildlife Service

Test Results

Organism Medium Spec. Route Lifestage Sex Effect Effect Comments

BIRD

LD50 LD50 reported as higher than 1000mg/kg.

References

Primary Reference : **AECTCV**
Archives of Environmental Contamination and Toxicology, 12, 355-382, (1985)

Secondary Reference : **!SIDSP***
OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Substance

Chemical Name :
 Reported Name : **NICOTINIC ACID**
 CAS Number : **59-67-6**

Area Type Subject Spec. Description Level / Summary Information :

CSK	REG	USE	AGRIC	PRMT	SUBSTANCE IS APPROVED AS PESTICIDE. SPECIFIC USES, LIMITATIONS AND SAFETY PRECAUTIONS ARE GIVEN. <u>Title :</u> LIST OF PERMITTED CHEMICALS FOR PLANT PROTECTION. <u>Reference :</u> SPPOR*, 290, 1990 <u>Effective Date :</u> JAN1991 SEZNAM POVOLENYCH PRIPRAVKU NA OCHRANU ROSTLIN (LIST OF PERMITTED CHEMICALS FOR PLANT PROTECTION) <u>Last Amendment :</u> <u>Entry / Update :</u> DEC1991
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Substance

Chemical Name :
 Reported Name : **NICOTINIC ACID**
 CAS Number : **59-67-6**

Area Type Subject Spec. Description Level / Summary Information :

RUS	REG	AIR	OCC	MAC CLASS	CLV: 1.0MG/M3 (AEROSOL) HAZARD CLASS: II <u>Title :</u> <u>Reference :</u> <u>Effective Date :</u> 01JAN1989 <u>Last Amendment :</u> GOSTS*, 12.1.005, 1988 <u>Entry / Update :</u> MAY1990 GOSUDARSTVENNYI STANDART SSSR (STATE STANDARD OF USSR)
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Substance

Chemical Name :
 Reported Name : **niacin**
 CAS Number : **59-67-6**

Area Type Subject Spec. Description Level / Summary Information :

EEC	REG	FOOD LABEL	- CONSM	PRMT RQR	A NUTRITION CLAIM IS PERMITTED FOR THIS SUBSTANCE. WHERE NUTRITION LABELLING IS PROVIDED, THERE ARE REQUIREMENTS CONCERNING THE INFORMATION TO BE GIVEN TO THE CONSUMER INCLUDING MASS CATERERS. <u>Title :</u> COUNCIL DIRECTIVE OF 24 SEPTEMBER 1990 ON NUTRITION LABELLING FOR FOODSTUFFS. (90/496/EEC) <u>Reference :</u> OJEC**, L276, 40, 1990 <u>Effective Date :</u> Official Journal of the European Communities <u>Last Amendment :</u> <u>Entry / Update :</u> 1991
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