## SIDS INITIAL ASSESSMENT PROFILE

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| **CAS No.** | - |
| **Chemical Name** | ***N*-(2-Octadecanoylaminoethyl)octadecanamide - Commercial Grade.**<br>A mixture of approximately 40% w/w *N*-(2-Octadecanoylaminoethyl)octadecanamide (CAS No. 110-30-5), 40% w/w *N*-(2-Octadecanoylaminoethyl)hexadecanamide (CAS No. 5136-44-7) and 13% w/w *N*-(2-Hexadecanoylaminoethyl)hexadecanamide (CAS No. 5518-18-3) |
| **Structural Formula** | $CH_3(CH_2)_xCONHCH_2CH_2NHCO(CH_2)_yCH_3$ x & y = 16:<br>*N*-(2-Octadecanoylaminoethyl)octadecanamidex = 16, y = 14:<br>*N*-(2-Octadecanoylaminoethyl)hexadecanamidex & y = 14:<br>*N*-(2-Hexadecanoylaminoethyl)hexadecanamide |

## SUMMARY CONCLUSIONS OF THE SIAR

This assessment has been performed for the commercial grade of N-(2-Octadecanoylaminoethyl)octadecanamide, which is a mixture of three homologues, as described below. Where data are available for pure N-(2-Octadecanoylaminoethyl)octadecanamide, they have also been incorporated into the assessment.

Commercially, N-(2-Octadecanoylaminoethyl)octadecanamide is manufactured from the reaction between octadecanoic acid and ethylenediamine. Industrially-produced octadecanoic acid is obtained by extraction from animal fat or from hydrogenation of vegetable oils and is actually a mixture of octadecanoic acid and hexadecanoic acid. In turn, commercial grades of N-(2-Octadecanoylaminoethyl)octadecanamide do not contain the pure substance alone, but are a mix of N-(2-Octadecanoylaminoethyl)octadecanamide (CAS No. 110-30-5, approximately 40% w/w), N-(2-Octadecanoylaminoethyl)hexadecanamide (CAS No. 5136-44-7, approximately 40% w/w) and N-(2-Hexadecanoylaminoethyl)hexadecanamide (CAS No. 5518-18-3, approximately 13% w/w) with other fatty acid amides and residual fatty acids making up the remainder of the mixture.

**Human Health**

No information on toxicokinetics or metabolism is available.

The inhalation $LC_{50}$ is > 112 mg/m$^3$ for 6-hr exposure in rats. The oral $LD_{50}$ (rat) is > 2000 mg/kg bw. For pure *N*-(2-Octadecanoylaminoethyl)octadecanamide (99.7% w/w) the oral $LD_{50}$ (rat) is > 2000 mg/kg bw. A dermal $LD_{50}$ (rabbit) of > 2000 mg/kg is reported in the secondary literature.

Based on information available in the secondary literature, the mixture is reported to be slightly irritating to the rabbit eye and skin in several studies. The majority of studies, however, do not indicate an irritant potential. Based on a weight of evidence approach, the mixture is considered to be non-irritant. No information is available concerning sensitisation in animals.

In a 28-day repeated dose toxicity study [OECD TG 407], rats were administered the mixture by gavage at a dose of 0 (vehicle), 100, 300 or 1000 mg/kg bw/day. No treatment-related effects were

observed in males or females in any of the dose groups. The NOAEL was 1000 mg/kg bw/day for both male and female rats in this study. In a similar study [Japanese Guideline] rats were administered pure *N*-(2-Octadecanoylaminoethyl)octadecanamide (99.7% w/w) by gavage at a dose of 0 (vehicle), 100, 300 or 1000 mg/kg bw/day. No treatment-related effects were observed in males or females in any of the dose groups. The NOAEL was 1000 mg/kg bw/day for both male and female rats in this study.

The mixture was not mutagenic in bacteria [OECD TG 471] and did not induce chromosomal aberrations in mammalian cells *in vitro* [OECD TG 473] either with or without metabolic activation. Pure *N*-(2-Octadecanoylaminoethyl)octadecanamide (99.7% w/w) was also not mutagenic in bacteria [OECD TG 471] and did not induce chromosomal aberrations in mammalian cells in vitro [OECD TG 473] either with or without metabolic activation.

No information is available for carcinogenicity.

In a reproduction/developmental toxicity screening test [OECD TG 421] rats were administered the mixture by gavage at a dose of 0 (vehicle), 100, 300 or 1000 mg/kg bw/day. Males were dosed for a total of 47 days, from 14 days before mating, and females were dosed from 14 days before mating to day 4 of lactation (42-52 days). No treatment-related general toxicity effects were observed in males or females in any of the dose groups. The NOAEL was 1000 mg/kg bw/day for both male and female rats in this study. In parental males, there were no significant changes in the absolute and relative weights of the testes and epididymides in any dose group. In parental females, no changes attributable to the mixture were noted in estrous cycle, copulation index, pairing days until copulation, fertility index, number of corpora lutea and implantation sites, implantation index, gestation length and index or in delivery and lactation states in any of the dose groups. In offspring, no changes attributable to the mixture were noted in the numbers of pups born and pups alive per litter, delivery index, live birth index, sex ratio, body weight of live pups on day 0 or day 4 of lactation, viability index, general condition or autopsy in any of the dose groups. The NOAEL for reproductive/developmental toxicity was 1000 mg/kg bw/day in this study. Overall N-(2-octadecanoylamidoethyl)octadecanamide is not considered to be a reproductive or developmental toxicant.

**Environment**

The mixture is a solid at room temperature. Melting point is 140-141°C (pure (N-(2-Octadecanoylaminoethyl)octadecanamide). Decomposition occurs at 260°C prior to boiling. Vapour pressure is 1.68E-15 - 2.95E-14 hPa (25°C, MPBPWIN v1.41) and log Kow is anticipated to be >6. Measured water solubility is < 0.0049 mg/L. The mixture is not expected to be hydrolyzed under normal environmental conditions. Indirect photo-oxidation by hydroxy radicals in the atmosphere is predicted to occur with a half-life of 1.82 – 1.98 hours (AOPWIN v1.91). The mixture is not readily biodegradable under aerobic conditions (BOD = 1.1%). The estimated BCF is 263 (BCFWIN v2.15) indicating low potential for bioaccumulation. This result should be treated with caution as it is based on a limit value for log Kow. Fugacity Model Mackay level III calculations indicate that the mixture will be distributed mainly to the soil (82.2%) and sediment (15.6%) compartments if released to air. If released to water, the mixture will distribute mainly to sediment (93.6%). If released to soil, the mixture will be distributed almost exclusively to the soil compartment (99.9%). If released simultaneously to air, soil and water, the mixture will be distributed mainly to sediment (58.3%) and soil (37.7%) compartments. These results should be treated with caution as they are based on a limit value for log Kow. Henry's Law constant is 1.49E-07 - 8.47E-08 (HENRYWIN v3.10) atm.$m^3$/mole.

Acute toxicity to fish (*Oryzias latipes*)(96-h $LC_{50}$) is > 0.027 mg/L (limit of solubility). Acute toxicity to *Daphnia Magna* (48-h $EC_{50}$) is > 0.0022 mg/L (limit of solubility). Acute toxicity to green algae (*Pseudokirchneriella subcapitata*) is $E_bC_{50}$ (0-72h) and $E_rC_{50}$ (24-72h) > 0.018 mg/L (limit of solubility). The chronic toxicity in *Daphnia magna* is 21-d $EC_{50}$ (reproduction) and NOEC (reproduction) > 0.0056 mg/L, 21-d $LC_{50}$ (parental) > 0.0056 mg/L (limit of solubility). The NOEC values in green alga (*Pseudokirchneriella subcapitata*) are $NOEC_b$ (0-72h) and $NOEC_r$ (24-72h) > 0.018 mg/L (limit of solubility). This mixture is considered to be of low hazard to the aquatic environment as no adverse effects were observed at the limit of solubility in any of the ecotoxicity

tests that have been conducted.

No information was identified concerning toxicity to soil or sediment dwelling organisms.

**Exposure**

Annual domestic production and imported amounts in Japan was approximately 100,000 tons in 2004. The mixture is used as an internal lubricant to improve the fluidity of plastics during processing, as an internal mold release agent and as an additive for paints and lacquers. The amount of the mixture used in plastics is up to 1% w/w. The main uses of plastics containing the mixture are in electronics equipment and automobile bumpers. The mixture is also approved for use as an additive in food contact materials in the US and EU. No consumer use is known for the mixture.

Occupational exposure to the mixture can occur mainly by inhalation at the production and user sites during operations. The atmospheric concentration was measured at one production site in Japan. A maximum concentration of 20 $mg/m^3$ was recorded during packaging of granulated product however operators wear overalls, gloves, helmets, protective eye goggles and disposable masks during all operations in order to minimize their exposure to the substance. Consumer exposure to the mixture can occur, mainly by the dermal route, through contact with a variety of finished products which contain the mixture. No information is available on the level of exposure.

The mixture may enter the environment at the production site and at chemical industries manufacturing the downstream products. In addition the mixture may enter into the environment through disposal via landfill of consumer products, such as electronics equipment, automobile bumpers and waste packaging materials. Release to the environment from disposed products is limited due to its low water solubility.

## RECOMMENDATIONS AND RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

**Human Health**: The chemical is currently of low priority for further work because of its low hazard potential.

**Environment**: The chemical is currently of low priority for further work because of its low hazard potential.