DRAFT PROPOSAL FOR CADMIUM GUIDELINE IN CHILDREN'S JEWELLERY

Document for Public Comment

Consumer Product Safety Directorate
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1. Executive Summary

Health concerns over cadmium in children's jewellery began after analytical testing by Health Canada revealed certain low-cost children's jewellery contained cadmium at levels up to 93%. It has been demonstrated, with tragic consequences, that swallowed jewellery may become lodged in the stomach, leading to the release of large amounts of lead in certain cases. Although no reported incidents of cadmium poisoning were found following ingestion of jewellery, it is possible this may pose an analogous threat, owing to the known toxicity of cadmium. Young children under the age of 4 commonly place non-food items in their mouths, and therefore represent the group most at risk.

The incidental ingestion of a piece of jewellery must be considered carefully from a risk assessment perspective, especially since acute exposure limits have not been well defined for cadmium. A review of the toxicological literature revealed that no reliable human data existed in order to define an acceptable one-time ingestion of cadmium. Therefore, results from animal studies were used to derive an oral acute provisional minimal risk level (pMRL) of 0.0732 mg/kg bw for cadmium.

Health Canada analyzed approximately 200 children's jewellery samples that were judged small enough to fit into a child's mouth for cadmium content. A subset of these samples were also subjected to migration testing, which revealed no consistency between the total amount of cadmium in a sample, and the amount that might be released in the simulated physiological environment of the stomach over an extended period (such as in the case of a piece of jewellery lodged in the stomach over several days). Since standardized migration testing cannot accurately predict the amount of cadmium that might be leached out of a sample in such an environment, using total cadmium content to derive a guideline is considered the most health-protective approach.

Based on a conservative weight of evidence approach, it is proposed that 130 ppm (0.013%) should protect small children from the risk of acute toxicity from cadmium following ingestion.

In addition, while risks associated with daily licking or sucking of a piece of cadmium-containing jewellery were not the primary focus of this report, a level of 130 ppm total cadmium should also be protective for chronic effects attributable to cadmium.

Note: 130 parts per million (ppm) = 130 mg/kg as a product concentration

2. Introduction

In 2009 and 2010, as part of Health Canada's cyclical enforcement surveys of children's jewellery, analytical testing revealed that in addition to lead, cadmium was also present in some articles of children's jewellery at levels up to 93% (930000 ppm). Since cadmium is a heavy metal with known toxicity, there is a potential risk in children's jewellery, the Consumer Product Safety Directorate of Health Canada (hereafter referred to as Health Canada) has undertaken a risk assessment of cadmium in children's jewellery in order to propose a product specific guideline.

3. Background

The issue of cadmium exposure from children's jewellery followed concerns over another heavy metal, lead. In 2006, a 4-year-old US child (Minneapolis, Minnesota) died from acute lead poisoning after swallowing a bracelet containing 99.1% lead (CDC, 2006). This case and others have demonstrated that swallowed jewellery may become lodged in the stomach, which may lead to the release of large amounts of lead (potentially much greater than that predicted by standard migration testing). Although no cases of cadmium poisoning have been reported following the ingestion of jewellery, it is possible this poses an analogous risk, owing to the known toxicity of this heavy metal.

Regulatory measures to limit the amount of lead in children's jewellery exist in Canada (*Children's Jewellery Regulations* under the *Canada Consumer Product Safety Act*) and the United States (*Federal Hazardous Substances Act – Interim Policy*, 2005; *Consumer Product Safety Improvement Act*, 2008).

4. Objectives

The objective of this report is to quantify the acute risk associated with a one-time ingestion of a cadmium-containing piece of jewellery by a small child, and to define an protective level of cadmium in children's jewellery.

In addition, chronic risks associated with daily licking or sucking of cadmium-containing jewellery intended for children will be evaluated.

5. Existing Exposure Limits

Since the focus of this assessment is on acute poisoning following ingestion of a piece of cadmium-containing jewellery, only oral exposure is considered. Several chronic exposure limits exist for ingested cadmium, which are mainly based on renal toxicity:

- World Health Organization (WHO) Provisional Tolerable Monthly Intake level (PTMI) – 25 µg/kg/month (**0.8 µg/kg bw/day**) (JECFA, 2010).
- U.S. Environmental Protection Agency (EPA) oral reference dose (RfD) – **1 µg/kg bw/day** for food intake and **0.5 µg/kg bw/day** for cadmium in drinking water (EPA, 1994).
- Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk level (MRL) for chronic oral exposure – **0.1 µg/kg bw/day** (ATSDR, 2008). ATSDR MRL for intermediate length exposure – **0.5 µg/kg bw/day** based on effects on bone in experimental animals

6. Review of Toxicological Results (Hazard Characterization)

In 2008, ATSDR published a draft Toxicological Profile for Cadmium, in which an exhaustive scientific review of cadmium toxicity was conducted (ATSDR, 2008). Scientific literature since the release of the ATSDR profile (i.e. 2008 – present) was consistent overall with regards to the acute toxicity of cadmium. Therefore, the ATSDR profile is considered the most comprehensive review of cadmium available, and was used as a source document to evaluate acute hazards following oral exposure. Selected cases are presented as follows.

Only anecdotal cases of acute cadmium poisoning have been documented in humans. The most notable reported case described an unknown number of children who experienced nausea, vomiting, abdominal cramps and headache following consumption of vending machine beverages that contained approximately 16 mg/L cadmium (Nordberg et al. 1973). The dose that induced these toxic effects was estimated to be 0.07 mg/kg (assuming ingestion of 150 mL and body weight of 35 kg). Although informative, a high level of uncertainty surrounded this case, and therefore it was not considered adequate to derive an exposure limit.

From documented studies in animals, a range of health endpoints was identified, including death, changes in body weight, as well as renal, hepatic, cardiovascular, hemotological, neurological, reproductive/developmental, and immunological effects. In addition, acute gastrointestinal toxicity appears to be a common endpoint consistent with that of the human poisoning noted above.

The most suitable study for derivation of a critical endpoint was a short-term study in Sprague Dawley rats (Borzelleca et al. 1989). In this study, a subset of animals were administered either 1 or 10 consecutive daily doses of cadmium chloride ($CdCl_2$) by oral gavage (0, 25, 51, 107, 225 mg/kg). Additional animals were administered $CdCl_2$ in drinking water for 10 days (calculated doses of 0, 1.8, 12.8, 18.2 mg/kg/day for males, 0, 1.8, 13.3, 22.6 mg/kg/day for females).

In the 1-day gavage portion of the study (0, 25, 51, 107, 225 mg/kg), mortality was observed in 0/20, 2/20, 1/20, 3/20, and 5/20 animals, respectively. Body weights were decreased, and lung weights increased in treated males relative to controls. Otherwise, no significant gross pathological findings were observed at necropsy, and there were no consistently significant dose-related adverse effects noted aside from a reported decrease in serum ALP levels (data not presented). Following 10 consecutive daily gavage doses (0, 25, 51, 107, 225 mg/kg), mortality was observed in 0/20, 3/20, 7/20, 7/20, and 20/20 animals, respectively. In remaining animals, body weight gains were reduced in a dose-related manner. Treatment-related changes were also noted for several serum chemistry (ALP, cholesterol and phosphorus), hematology (hemoglobin, hematocrit, erythrocyte, leukocytes and platelets) parameters, as well as signs of toxicity in liver, brain, spleen, lungs, thymus and kidneys. The authors concluded that 25 mg/kg/day was the apparent No-Observed-Adverse-Effect-Level (NOAEL).

There were no deaths in the 10-day drinking water study (calculated doses of 0, 1.8, 12.8 and 18.2 mg/kg/day for males, and 0, 1.8, 13.3 and 22.6 mg/kg/day for females). Dose-related body weight decreases were noted, although this may have been at least partly related to the reduced fluid intake by treated animals, presumably due to the poor palatability of cadmium in water, which has been previously demonstrated (Cory-Slechta et al. 1981). The authors reported no evidence of significant compound-related toxicity for rats treated via drinking water, and considered the highest dose (18–23 mg/kg/day) the apparent NOAEL. It is acknowledged that minor changes were observed

related to testes, kidney, liver, spleen and thymus, as well as for other serum chemistry parameters (ALP, 5'-nucleotidase, protein, glucose, and BUN), but these were most typically observed at the high dose only. In addition, the toxicological significance of these findings was unclear, and may have been a secondary signs of reduced food intake, which could not be verified as this parameter (i.e. food intake) was not measured on the study.

However, for the purposes of the Health Canada assessment, the NOAEL for the above study (Borzelleca et al. 1989) was considered to be the mid-dose (12.8 and 13.3 mg/kg/day for males/females, respectively), as an added measure of precaution.

Therefore, in the absence of reliable human data, 12.8 mg/kg ($CdCl_2$) was chosen as the most appropriate acute critical effect level.

7. Characterization of Minimal Risk Level

From the critical effect level described above (12.8 mg/kg bw – $CdCl_2$), a provisional minimum risk level (pMRL) can be calculated for cadmium chloride:

$$\text{pMRL} = \frac{12.8 \text{ mg/kg bw}}{10 \text{ (intra)} \times 10 \text{ (inter)}} = 0.12 \text{ mg/kg bw}$$

To determine exposure attributable to elemental cadmium (which accounts for 61% of $CdCl_2$; MW Cd = 112; MW Cl_2 = 70), the pMRL was adjusted as follows:

$$\text{pMRL} = 0.12 \text{ mg/kg bw} \times 0.61 = 0.0732 \text{ mg/kg bw}$$

Therefore, for the purpose of this assessment, 0.0732 mg/kg bw is considered to be a health protective exposure value with regards to a one-time oral ingestion of elemental cadmium.

8. Child's Exposure Following Ingestion of a Piece of Children's Jewellery

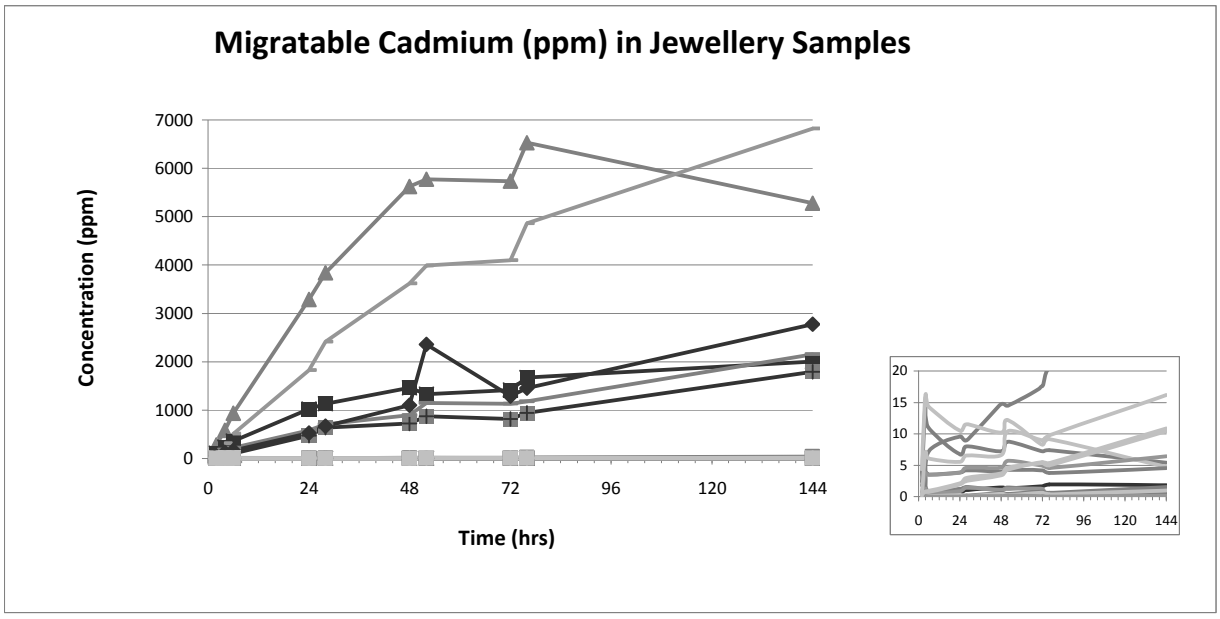
Young children under the age of 4 commonly place non-food items in their mouths, and therefore represent the group most likely to ingest a piece of jewellery. Using 13 kg as the average body weight for a child 7 months to 4 years (Health Canada, Human Health Risk Assessment for Priority Substances, 1994), an incidental intake of cadmium at the pMRL for this age group can be calculated as follows:

0.0732 mg/kg bw x 13 kg = 0.9516 mg

9. Total Cadmium Content versus Migration

In 2009, the Product Safety Laboratory (PSL) of Health Canada conducted analyses of migratable cadmium in metallic jewellery over 144 hours (project # 2009-1123). Additional analyses of children's jewellery were performed in 2009 (project 2009-1193) for total cadmium concentrations in a larger number of children's jewellery products. In 2010, samples from project 2009-1193 that contained total cadmium levels greater than 100000 ppm (10%) were subjected to extended migration testing (project 2010-1290). This extended testing interval (i.e. 144 hours) was selected in order to show that migration of cadmium from children's jewellery might continue after 2 hours (which is the standard sampling time for migration testing under internationally recognized guidelines such as EN71-3). Results are presented in the following figure.

Figure 1 Migratable Cadmium in Jewellery Samples over 144 hours

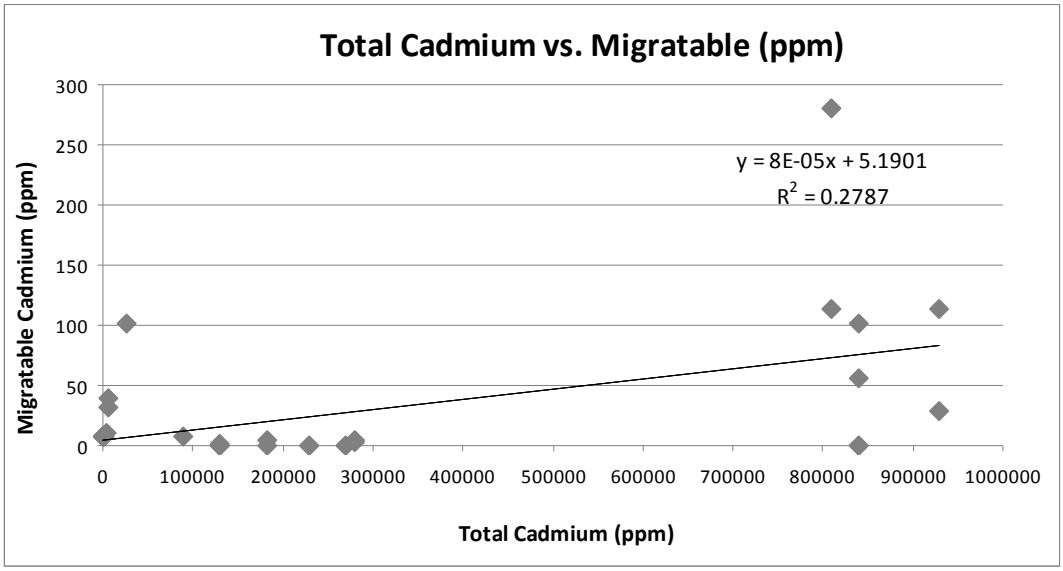


These results demonstrate that for many samples (reduced-scale graph, bottom right), the 2-hour timeframe may be adequate to predict migration. For several others however (full-scale graph), cadmium continued to migrate in the simulated physiological environment of the stomach (HCl at 37°C) following the 2-hour time point. This suggests that using a 2-hour migration test may grossly

underestimate cadmium exposure via jewellery lodged in the stomach over the course of several days, as was observed in the lead-poisoning death in 2006.

Data from PSL project reports 2009-1123 and 2009-1193 was analyzed to compare total cadmium content with migration results after 2-hours. Results are presented in the following figure.

Figure 2 Total Cadmium versus Migratable Cadmium



The above results show no clear correlation between the total amount of cadmium in a jewellery sample, and the amount that might migrate out of the sample in the acidic environment of the stomach over time. Therefore, any exposure scenario based on migration out of a jewellery sample will potentially underestimate exposure to cadmium. Hence, it is considered that cadmium limits in children's jewellery should focus on total cadmium, and not migratable levels.

10. Proposed Guideline for Cadmium in Children's Jewellery

Health Canada compiled the weights of 94 children's jewellery samples that were considered small enough to fit into a child's mouth (considered a "small part" according to methodologies specified in certain regulations under the *Canada Consumer Product Safety Act*, see Appendix 1). The 95th percentile weight from this set of samples was 7.31 g (mean 2.8 g). Therefore, 7.31 g (0.0073 kg) represents a conservative estimate of the heaviest piece of jewellery that might be ingested by a small child. Since regulatory limits are product based, total allowable cadmium concentrations derived using the heaviest piece of jewellery (i.e. containing the largest total amount of cadmium) would be most protective.

Therefore:

$$\frac{0.9516 \text{ mg}}{0.0073 \text{ kg}} = 130 \text{ ppm } (0.013\ \%)$$

Thus, it is considered that a total cadmium concentration in children's jewellery of 130 ppm (0.013%) would protect small children from the risk of acute toxicity following ingestion. *Note: 130 parts per million (ppm) = 130 mg/kg as a product concentration*

11. Chronic Risks Associated with Children's Jewellery

The risk associated with chronic oral exposure from licking or sucking a piece of children's jewellery containing cadmium must be evaluated separately, as the exposure scenario does not include prolonged direct contact of the jewellery item with stomach acid (HCl) under physiologic conditions.

The amount of cadmium that might be released in such a scenario can be reasonably estimated by a saliva surrogate, such as water. In Product Safety Laboratory project reports 2009-1123 and 2010-1290, migration of high content cadmium jewellery (total content up to 93%) into water was measured for extended periods. From all tested samples, the highest level of migration following 2-hours in water was 13.5 ppm (13.5 mg/kg). Using the same reasoning as above, a 7.31 g piece of jewellery could potentially release 0.1 mg (=13.5 mg/kg x 0.0073 kg).

For a child aged 7 months to 4 years old (13 kg):

0.1 mg/13 kg = 0.0077 mg/kg bw

Therefore, a child licking or sucking a piece of cadmium containing jewellery **every day for 2 hours** could be potentially exposed at a level of 0.0077 mg/kg bw/day (7.7 µg/kg bw/day). While this is a conservative estimate, this level is considerably higher than the chronic oral exposure limits described in Section 2 of this report (ranging from 0.1 to 1 µg/kg bw/day).

Levels of cadmium in some children's jewellery may therefore also pose an unacceptable risk for chronic effects. However, it is acknowledged that the poor palatability (i.e. bad taste) of cadmium may reduce the likelihood of a child licking/sucking of a piece of high-content cadmium jewellery on a regular basis.

12. Proposed Guideline with Regards to Chronic Risks

Chronic risks should be eliminated by the substantial reduction of total cadmium levels in children's jewellery to 130 ppm (0.013%), as proposed in the previous section. As a hypothetical scenario, assume that a 7.31 g piece of jewellery (i.e. heaviest ingestible) contains 130 ppm total cadmium (130 mg/kg):

130 mg/kg x 0.0073 kg = 0.950 mg = 950 µg

This means that under the proposed guideline of 130 ppm, a piece of ingestible jewellery should not contain more than 950 µg total cadmium. As discussed in the previous example, the highest 2-hour (water) migration value was 13.5 ppm (13.5 mg/kg). For the purpose of this report, this value can also be expressed as a ratio (i.e. 13.5 mg/kg x 1 kg/1000000 mg = 0.0000135).

Therefore, the theoretical maximum amount of cadmium that might migrate out of such a sample can be calculated:

950 µg x 0.0000135 = 0.0128 µg

For a child aged 7 months to 4 years old (13 kg):

0.0128 µg/13 kg = 0.001 µg/kg bw

Since this calculated exposure (0.001 µg/kg bw or 0.001 µg/kg bw/day) is much lower than the chronic oral exposure limits described previously (0.1 to 1 µg/kg bw/day), the above hypothetical example demonstrates that a reduction in the total cadmium content of jewellery to 130 ppm would be protective of chronic effects attributable to cadmium.

13. Conclusion

A total cadmium concentration in children's jewellery of 130 ppm (0.013%) would protect small children from the risk of acute toxicity following ingestion, and of chronic toxicity from daily mouthing of jewellery.

Note: 130 parts per million (ppm) = 130 mg/kg as a product concentration

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APPENDIX 1 – Sample Weights

Project 2008-1075

Sample Number	Description	Sample Weight (g)
S-1008708-G1	loop chain/attached chain	0.6941
S-1008708-H1	loop chain/attached chain	0.494
S-1008708-I1	loop chain/attached chain	0.6774
S-1008708-B1	moon pendant	2.5363
S-1008708-B2	moon pendant	2.553
S-1008708-B3	moon pendant	2.582
S-1008483-B1	fake tongue piercing	0.8669
S-1008483-C1	fake tongue piercing	0.8603
S-1008483-D1	fake tongue piercing	0.875
S-1008518-B1	purple penguin pendant	1.5926
S-1008518-C1	black penguin pendant	1.2985
S-1008518-D1	green frog pendant	1.432
S-1008531-B1	chrome chain	3.4669
S-1008643-B1	lady bug	7.9782
S-1008643-C1	lady bug	7.6214
S-1008643-D1	lady bug	7.3242
S-1008646-B1	small skull pendant	1.974
S-1008646-C1	eagle pendant	1.6597
S-1008646-D1	dragon pendant	4.008
S-1008389-B1	ring	3.375
S-1008389-C1	ring	3.4257
S-1008389-D1	ring	3.501
S-1008482-B1	ring-red	1.6092
S-1008482-C1	ring-blue	1.801
S-1008482-D1	ring-green	1.7725
S-1008484-B1	pendant-cross	2.1165
S-1008484-C1	pendant-cross	1.8733
S-1008484-D1	pendant-cross	1.9474
S-1008513-B1	pendant-love	2.752
S-1008513-C1	pendant-love	2.7668
S-1008513-D1	pendant-love	2.7775
S-1008385-E1	dolphin pendant	3.2597
S-1008385-F1	dolphin pendant	3.265
S-1008385-G1	dolphin pendant	3.2577
S-1008402-B1	ring – scorpion	1.476
S-1008402-C1	ring – scorpion	1.375
S-1008402-D1	ring – person	1.4497
S-1008449-B1	pink cat pendant – friends	1.4143
S-1008449-C1	yellow cat pendant – best	1.4486
S-1008449-D1	blue flower pendant – best	1.0192

Project 2009-1193

Sample Number	Description	Sample Weight (g)
S-1009859-B1	Pink cupcake shoe tag	6.7232
S-1009859-C1	Pink cupcake shoe tag	6.9661
S-1009859-D1	Pink cupcake shoe tag	6.8182
S-1009860-B1	Lady Bug shoe tag	7.5006
S-1009860-C1	Lady Bug shoe tag	7.7161
S-1009860-D1	Lady Bug shoe tag	7.3003
S-1009862-B1	Mood ring	1.3173
S-1009862-C1	Mood ring	1.3492
S-1009862-D1	Mood ring	1.1943
S-1009874-B1	Red toe ring	0.5587
S-1009874-B2	Green toe ring	0.5551
S-1009874-B3	Yellow toe ring	0.568
S-1009879-B1	Cat earring	0.6851
S-1009879-C1	Cat earring	0.6464
S-1009879-D1	Cat earring	0.6622
S-1009888-B	Metallic beads	6.7324
S-1009888-C	Metallic beads	6.8599
S-1009888-D	Metallic beads	6.6282
S-1009894-B	Silver key pendant	3.881
S-1009894-C	Silver key pendant	3.974
S-1009894-D	Silver key pendant	4.007
S-1009941-B	Toe mood ring	1.2873
S-1009941-C	Toe mood ring	1.1812
S-1009941-D	Toe mood ring	1.2826
S-1009943-B	"K" charm	1.5204
S-1009943-C	"K" charm	1.4863
S-1009943-D	"K" charm	1.4822

S-1008459-B1	lady bug pendant pink	1.7279
S-1008459-C1	lady bug pendant yellow	1.6402
S-1008459-D1	lady bug pendant yellow	1.8841
S-1008385-B1	dolphin pendant	3.231
S-1008385-B2	dolphin pendant	3.2384
S-1008385-B3	dolphin pendant	3.2648
S-1008403-B1	metalic ring with flowers	1.5233
S-1008403-B2	metalic ring with flowers	1.8323
S-1008403-B3	metalic ring with flowers	1.7291
S-1008409-B1	ring for ear/nose	0.3669
S-1008409-B2	ring for ear/nose	0.3688
S-1008409-B3	ring for ear/nose	0.3704
S-1008434-B1	spider ring yellow	6.2138
S-1008434-B2	spider ring yellow	6.3878
S-1008434-B3	spider ring white	6.7235
S-1008395-B1	purple butterfly	2.5566
S-1008395-C1	pink butterfly	2.8383
S-1008395-D1	pink butterfly	2.869
S-1008403-B1	metallic ring	1.8723
S-1008403-C1	metallic ring	1.7613
S-1008403-D1	metallic ring	1.8484
S-1008409-B1	body jewellery Small	0.3334
S-1008409-C1	body jewellery Medium	0.3726
S-1008409-D1	body jewellery Large	0.431
S-1008434-B1	spider ring Red	6.1875
S-1008434-C1	spider ring Green	7.1776
S-1008434-D1	spider ring Purple	6.1987

Combined Results

Mean	2.808616
Standard deviation	2.241959
Minimum	0.3334
Maximum	7.9782
Number of samples	94
95th percentile	7.308665
90th percentile	6.79246
10th percentile	0.59152